PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PrIlumya®

Tildrakizumab injection

100 mg in 1 mL sterile solution (100 mg/mL) for subcutaneous injection

Interleukin-23 (IL-23) inhibitor, ATC code: L04AC17

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RECENT MAJOR LABEL CHANGES

Not Applicable

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Ilumya® (tildrakizumab injection) is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

1.1 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (≥ 65 years of age): Limited data did not indicate differences in safety or efficacy in elderly patients compared to younger patients (see 7.1.4 Geriatrics).

2 CONTRAINDICATIONS

- Ilumya (tildrakizumab injection) is contraindicated in patients who are hypersensitive to tildrakizumab or to any ingredient in the formulation, including any non-medicinal ingredients, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Ilumya (tildrakizumab injection) should be initiated and supervised by healthcare professionals experienced in the diagnosis and treatment of plaque psoriasis and familiar with the Ilumya efficacy and safety profile. Patients may self-inject Ilumya if a healthcare professional determines that it is appropriate.

4.2 Recommended Dose and Dosage Adjustment

The recommended dose of Ilumya is 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

Pediatrics (<18 years of age)

Health Canada has not authorized an indication for pediatric use.

Geriatrics (≥65 years of age)

Safety and efficacy data in patients aged 65 years and older are limited. No dose adjustment is required.

Duration of treatment

Continuation of Ilumya should be reconsidered if a patient has not responded within 28 weeks of treatment onset.

4.4 Administration

Ilumya is administered by subcutaneous injection. Ilumya can be injected by a healthcare professional or, after proper training in subcutaneous injection technique, patients may self-inject Ilumya if a healthcare professional determines that it is appropriate. However, the physician should ensure appropriate follow-up of patients.

Full instructions for use are provided in the package leaflet.

Injections should not be administered into areas where the skin is tender, bruised, erythematous, indurated, or affected by psoriasis.

Ilumya does not contain any preservatives. Therefore, discard any unused product remaining in the pre-filled syringes or pre-filled pens (see 11 STORAGE, STABILITY AND DISPOSAL). The full amount of Ilumya 100 mg pre-filled syringe or pre-filled pen should be injected for each dose according to the directions provided in the respective "Instructions for Use" document.

4.5 Missed Dose

Patients who miss a dose of Ilumya should be advised to inject this missed dose as soon as they become aware of it, and then follow with their next scheduled dose.

5 OVERDOSAGE

In the event of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment be instituted immediately. Single doses up to 10 mg/kg intravenously have been administered in clinical trials without dose-limiting toxicity**.**

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 - Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-Medicinal Ingredients
Subcutaneous (SC) injection	Sterile solution in a single-dose pre-filled syringe or pre-filled pen (100 mg / 1 mL)	L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, water for injection

Ilumya (tildrakizumab injection)**,** for subcutaneous use, is a sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution.

Ilumya is supplied in a single-dose (100 mg) pre-filled syringe with a glass barrel and 29-gauge fixed, ½-inch stainless-steel needle. Each pre-filled syringe is equipped with a passive needle guard and a needle cover.

Ilumya is also supplied in a single-dose (100 mg) pre-filled pen, with a syringe barrel of Type I glass, a staked/bonded needle, a rigid needle shield and a sterile ready to use plunger stopper.

Ilumya is available in cartons containing one pre-filled syringe or one pre-filled pen per carton.

7 WARNINGS AND PRECAUTIONS

Infections

Ilumya is an immunomodulatory agent which has the potential to increase the risk of infection. In clinical trials, there was no increased risk of infection in subjects treated with Ilumya relative to placebo; however, patients with active infections or a history of recurrent infections were not included in clinical trials. Ilumya should not be given to patients with any clinically important

active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, the risks and benefits should be considered prior to prescribing Ilumya. Patients should be instructed to seek medical advice if signs or symptoms of a clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy for the infection, the patient should be closely monitored and Ilumya should not be administered until the infection resolves (see 8.2 Clinical Trial Adverse Reactions).

Pre-treatment Evaluation for Tuberculosis

Ilumya must not be given to patients with active tuberculosis (TB). Evaluate patients for TB infection according to the Canadian TB Standards prior to initiating treatment with Ilumya. Initiate treatment of latent TB prior to initiating treatment with Ilumya. Consider anti-TB therapy prior to initiation of Ilumya in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving Ilumya should be monitored closely for signs and symptoms of active TB during and after treatment.

Immune

Hypersensitivity

Non-serious cases of urticaria occurred in Ilumya treated subjects in clinical trials. If a serious hypersensitivity reaction occurs, administration of Ilumya should be discontinued immediately and appropriate therapy initiated.

As with all therapeutic proteins including Ilumya, there is a potential for anaphylaxis. If an anaphylactic or other serious allergic reaction occurs, immediately discontinue the administration of Ilumya and initiate appropriate medical treatment.

Inform patients/caregivers of the signs and symptoms of anaphylaxis and hypersensitivity reactions, and instruct them to seek immediate medical care if signs and symptoms occur.

Vaccinations

Prior to initiating therapy with Ilumya, consider completion of appropriate immunizations according to current immunization guidelines. Patients treated with Ilumya should not receive live vaccines. No data are available on the response to live or inactive vaccines.

If a patient has received live vaccination (viral or bacterial), it is recommended to wait at least 4 weeks prior to starting treatment with Ilumya.

Sexual Health

Fertility

The effect of Ilumya on human fertility has not been evaluated. In addition, no dedicated fertility studies have been conducted in animals.

7.1 Special Populations

7.1.1 Pregnant Women

The use of Ilumya in pregnant women has not been studied. The effect of Ilumya on human pregnancy is unknown.

Human IgG1 is known to cross the placental barrier; therefore, tildrakizumab may be transferred from the mother to the fetus.

In two developmental studies conducted with pregnant cynomolgus monkeys, tildrakizumab was shown to distribute across the placental barrier as serum concentrations were quantifiable in fetal and neonatal monkeys.

In a pre- and postnatal development study conducted in pregnant cynomolgus monkeys, *in utero* exposure to tildrakizumab from a maternal subcutaneous dose of 100 mg/kg resulted in incidences of neonatal deaths due to infection (see 16 NON-CLINICAL TOXICOLOGY, Reproductive and Developmental Toxicology). Animal studies are not always predictive of human response; therefore, it is unknown whether Ilumya can cause fetal harm when administered to a pregnant woman.

Women of childbearing potential should use adequate contraception while using Ilumya and for at least 4 months after the last Ilumya dose.

7.1.2 Breast-feeding

There are no data on the presence of tildrakizumab in human milk, the effects on the breast fed infant, or the effects on human milk production. Because human immunoglobulin G (IgG) is secreted into human milk, precaution should be exercised.

In a pre- and postnatal development study, tildrakizumab was detected at low levels in the breast milk of monkeys dosed with tildrakizumab from gestation day 50 to parturition (see 16 NON-CLINICAL TOXICOLOGY, Reproductive and Developmental Toxicology).

A decision should be made whether to discontinue breast-feeding or to discontinue Ilumya taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4 Geriatrics

Geriatrics (≥ 65 years of age): Of the 1,238 patients with plaque psoriasis exposed to Ilumya in Phase 3 clinical trials, 109 (8.8%) were 65 years or older and 15 (1.2%) were 75 years or older. The limited safety and efficacy data available from patients aged 65 years and older do not suggest that a dosage adjustment is required in these patients.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The most frequently reported adverse drug reaction in Ilumya 100 mg treated patients during the 12-week, placebo-controlled period of the reSURFACE 1 and reSURFACE 2 studies was nasopharyngitis (3.2%).

The proportion of Ilumya-treated patients who discontinued treatment due to adverse events during the placebo-controlled period of reSURFACE 1 and reSURFACE 2 was similar for subjects receiving tildrakizumab 100 mg (0.5%) and placebo (1.0%).

The overall incidence of SAEs during the placebo-controlled period of reSURFACE 1 and reSURFACE 2 was similar for subjects receiving tildrakizumab 100 mg (1.5%) and placebo (1.6%).

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful for identifying and for approximating rates of adverse drug reactions in real-world use.

The safety profile of Ilumya in patients with moderate to severe plaque psoriasis is based on pooled data from two phase 3 trials (reSURFACE 1 and reSURFACE 2). A total of 1255 plaque psoriasis subjects were exposed to Ilumya 100 mg or 200 mg in these 2 trials (see 14 CLINICAL TRIALS). Of these, 642 subjects were exposed for at least 52 weeks, 587 for at least 78 weeks, 469 for at least 104 weeks, and 271 for at least 256 weeks to Ilumya 100 mg.

Table 2 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the Ilumya 100 mg group than the placebo group during the 12-week, placebo-controlled period of the pooled clinical trials, reSURFACE 1 and reSURFACE 2.

Table 2 - Adverse Reactions (regardless of causality) Reported by ≥1% in the Ilumya 100 mg Treatment Group and More Frequently than in the Placebo Group in the 12-week, placebo-controlled period of the reSURFACE 1 and reSURFACE 2 Trials

	Placebo		Ilumya 100 mg	
	n	(%)	n	(%)
Subjects in population	**310**		**616**	
with one or more adverse reactions	160	51.6	282	45.8
Gastrointestinal disorders				
Diarrhea	2	0.6	7	1.1
General disorders and administration site conditions				
Injection site reactions[1]	8	2.6	24	3.9
Fatigue	5	1.6	15	2.4
Infections and infestations				
Upper respiratory tract infections[2]	38	12.3	93	15.1
Musculoskeletal and connective tissue disorders				
Pain in extremity	2	0.6	6	1.0
Arthralgia	7	2.3	15	2.4
Nervous system disorders				
Headache	9	2.9	20	3.2

Note: Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
[1] High-Level Term 'Injection site reactions' includes: Injection site bruising, Injection site discomfort, Injection site dryness, Injection site erythema, Injection site hematoma, Injection site hemorrhage, Injection site hypoesthesia, Injection site pain, Injection site pruritus, Injection site reaction, Injection site swelling, Injection site urticaria
[2] High-Level Term 'Upper respiratory infections' includes: Acute sinusitis, Nasopharyngitis, Pharyngitis, Rhinitis, Sinusitis, Tonsillitis, Upper respiratory tract infection

Infections

In the placebo-controlled period of the Phase 3 clinical trials in plaque psoriasis (a total of 616 subjects treated with Ilumya 100 mg and 310 subjects treated with placebo for 12 weeks), infections were reported in 21% of subjects treated with placebo while 20.9% in subjects

treated with Ilumya 100 mg. Serious infections occurred in 0.2% of subjects treated with Ilumya 100 mg and in 0.3% of subjects treated with placebo.

Over the treatment period of up to 64 weeks in subjects treated with Ilumya 100 mg, infections were reported in 0.443 subjects per patient-year of exposure. Serious infections were reported in 0.009 subjects treated with Ilumya 100 mg per patient-year of exposure.

In the open-label, uncontrolled, extension period of the two Phase 3 clinical trials, infections were reported in 65.5% of subjects and serious infections in 3.7% of subjects treated with Ilumya 100 mg.

Hypersensitivity Reactions

No cases of drug-related anaphylaxis and few cases of urticaria (0.009 subjects treated with Ilumya 100 mg per patient-years of exposure) occurred in subjects treated in plaque psoriasis clinical trials with Ilumya 100 mg for up to 64 weeks (see 7 WARNINGS AND PRECAUTIONS, Immune, Hypersensitivity).

In the open-label, uncontrolled, extension period of the two Phase 3 clinical trials, no cases of drug-related anaphylaxis were reported. Two cases of drug-related hypersensitivity reactions (urticaria), were reported in subjects treated with 100 mg.

Immunogenicity

As with all therapeutic proteins there is the potential for immunogenicity with Ilumya. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Comparison of incidence of antibodies between products by different tests may be misleading.

At the end of the extension period of the two Phase 3 trials, 8.3% (51/615) of subjects developed antibodies to tildrakizumab. Of the subjects who developed anti-drug antibodies, 37% (19/51, or 3% of all subjects receiving Ilumya 100 mg) had neutralizing antibodies. Presence of neutralizing antibodies was associated with lower tildrakizumab concentrations and reduced efficacy.

Adverse Reactions through Weeks 52 and 64 and the extension period

Through Week 52 (Phase 2b and reSURFACE 2) and Week 64 (reSURFACE 1), the types and the frequency of the adverse reactions in the Ilumya-treated patients were similar to that observed during the first 12 weeks of treatment.

In the open-label extension period of the two Phase 3 clinical trials (with a median duration of exposures of 204 and 192 weeks, respectively), incidence rate of one or more adverse events was reported in 86.6% of the subjects, drug-related adverse events in 21.8% of the subjects, serious adverse events in 23.7% of the subjects, serious drug-related adverse events in 3.2% of the subjects, and discontinuation due an adverse events in 6.8% of the subjects treated with 100 mg dose. No new clinically significant safety signals were reported.

Adverse Reactions from a study of moderate to severe psoriasis of the scalp through Week 52

In a randomized placebo-controlled trial in 231 subjects with moderate to severe psoriasis of the scalp, the safety data was consistent with the known safety profile of tildrakizumab and did not present any new safety signals up to Week 52.

8.3 Less Common Clinical Trial Adverse Reactions

For System Organ Classes (SOCs) listed in Table 2, adverse reactions (regardless of causality) that occurred at rates <1% in the Ilumya 100 mg treatment group and more frequently than in the placebo group in the 12-week, placebo-controlled period of the reSURFACE 1 and reSURFACE 2 Trials include:

Gastrointestinal disorders: Abdominal discomfort, Abdominal pain, Abdominal pain lower, Abdominal pain upper, Dry mouth, Dyspepsia, Feces soft, Food poisoning, Hyperchlorhydria, Lip dry, Oesophageal polyp, Periodontal disease, Swollen tongue, Toothache, Vomiting

General disorders and administration site conditions: Chills, Feeling cold, Impaired healing, Malaise, Pain

Infections and infestations: Cellulitis, Conjunctivitis, Cystitis, Ear infection, Gingival abscess, Gingivitis, Hordeolum, Impetigo, Lower respiratory tract infection, Oral candidiasis, Oral herpes, Otitis externa, Papilloma viral infection, Rash pustular, Skin bacterial infection, Skin candida, Trichophytosis

Musculoskeletal and connective tissue disorders: Arthritis, Bursitis, Intervertebral disc degeneration, Muscle tightness, Muscular weakness, Myalgia, Periarthritis, Rheumatic disorder, Wrist deformity

Nervous system disorders: Alcoholic seizure, Dizziness, Dysgeusia, Hypertonia, Hypoaesthesia, Lethargy, Migraine with aura, Parosmia, Syncope, Tension headache, Visual field defect

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Live Vaccines

Live vaccines should not be given concurrently with Ilumya (see 7 WARNINGS AND PRECAUTIONS, Immune, Vaccinations).

Immunosuppression Therapy

The safety and efficacy of Ilumya in combination with other immunosuppressant drugs or with phototherapy have not been evaluated.

Interaction with CYP450 Substrates

The formation of cytochrome P450 (CYP) enzymes can be altered by increased levels of certain cytokines (e.g. interleukin [IL]-β, IL-6, tumour necrosis factor, and interferon) during chronic inflammation.

In a clinical pharmacology study in subjects with plaque psoriasis comparing pharmacokinetics of CYP probe substrates before and after administering 200 mg (2 times the recommended 100 mg dose) of tildrakizumab subcutaneously on Day 1 and Day 29, no clinically significant changes were seen in the pharmacokinetics of caffeine (CYP1A2 probe substrate), warfarin (CYP2C9 probe substrate), omeprazole (2C19 substrate), or midazolam (CYP3A4 substrate). The exposure (AUC_{inf}) of dextromethorphan (CYP2D6 substrate) increased by 20% after the two doses of tildrakizumab treatment at 200 mg.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Tildrakizumab is a humanized IgG1/k monoclonal antibody that binds to human interleukin 23 (IL-23) and inhibits IL-23 signaling in cell-based assays.

IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses.

10.2 Pharmacodynamics

No formal pharmacodynamics studies have been conducted with Ilumya.

10.3 Pharmacokinetics

Tildrakizumab pharmacokinetics increases proportionally over a dose range from 50 mg to 200 mg following subcutaneous administration in subjects with plaque psoriasis. Following administration of 100 mg of tildrakizumab at Week 0, 4, and every 12 weeks thereafter in subjects with moderate to severe psoriasis, the steady state was achieved by 16 weeks. The mean (± SD) steady-state trough concentrations ranged from 1.22 ± 0.94 mcg/mL to 1.47 ± 1.12 mcg/mL. The geometric mean (CV%) steady-state C_{max} was 8.1 mcg/mL (34%).

Absorption:

Following subcutaneous injection in healthy subjects, the absolute bioavailability of tildrakizumab was estimated to be 73-80%. The time to reach maximum concentration (T_{max}) was approximately 6 days after injection.

Distribution:

The geometric mean (CV%) volume of distribution is 10.8 L (24%).

Metabolism:

The metabolic pathway of tildrakizumab has not been characterized. As a humanized IgG1/k monoclonal antibody, tildrakizumab is expected to be degraded into small peptides and amino acids via catabolic pathways in a manner similar to endogenous IgG.

Elimination:

The geometric mean (CV%) systemic clearance was 0.32 L/day (38%) and the half-life was 23.4 days (23%) in subjects with plaque psoriasis.

Special Populations and Conditions

No clinically significant differences in the pharmacokinetics of tildrakizumab were observed based on age (18 to 82 years), based on a population pharmacokinetic analysis.

Body Weight:

Tildrakizumab concentrations were lower in subjects with higher body weight.

Hepatic Insufficiency:

No specific studies have been conducted to determine the effect of hepatic impairment on the pharmacokinetics of tildrakizumab.

Renal Insufficiency:

No specific studies have been conducted to determine the effect of renal impairment on the pharmacokinetics of tildrakizumab.

11 STORAGE, STABILITY AND DISPOSAL

Ilumya should be stored refrigerated at 2°C to 8°C in the original carton to protect from light until the time of use. DO NOT FREEZE OR SHAKE.

Ilumya can be transferred to room temperature storage (≤ 25°C) for up to 30 days in the original carton to protect from light until the time of use. Record the transfer date in the designated field provided on the carton. Once transferred to room temperature storage, do not place Ilumya back in the refrigerator. Use Ilumya within 30 days of transfer or by the expiry date printed on the carton, whichever occurs first. Do not store Ilumya above 25°C.

Ilumya must be kept out of reach and sight of children.

Ilumya is sterile and preservative-free. Discard any unused portion after injection.

12 SPECIAL HANDLING INSTRUCTIONS

Following administration of Ilumya, discard any unused portion. The syringe or pre-filled pen should be disposed of in a puncture resistant container. Patients or caregivers should be instructed on how to properly dispose of the syringe and needle or pre-filled pen and told not to reuse these items.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	tildrakizumab
Chemical name:	Anti-(human interleukin 23) immunoglobulin G1 (human-Mus musculus monoclonal heavy chain) disulfide with human-Mus musculus monoclonal light chain, dimer
Molecular formula and molecular mass:	Tildrakizumab is a humanized immunoglobulin G1/kappa (IgG1/κ) antibody with an average molecular weight of 144,144 Daltons
Physicochemical properties:	Ilumya, for subcutaneous use, is a clear to slightly opalescent, colorless to slightly yellow solution.

14 CLINICAL TRIALS

14.1 Clinical Trials by Indication

Plaque psoriasis

The efficacy and safety of Ilumya (tildrakizumab injection) was assessed in two Phase 3 multicenter, randomized, double-blind, placebo-controlled trials (reSURFACE 1 and reSURFACE 2). reSURFACE 1 and reSURFACE 2 enrolled a total of 1862 patients 18 years of age and older with plaque psoriasis who had a minimum body surface area involvement of 10%, a Physician Global Assessment (PGA) score of ≥3 in the overall assessment (plaque thickness, erythema, and scaling) of psoriasis on a severity scale of 0 to 5, a PASI score ≥12, and who were candidates for phototherapy or systemic therapy. Patients with non-plaque forms of psoriasis (e.g., erythrodermic, pustular, guttate) were excluded from the studies. Randomization was stratified by body weight (≤90 kg or >90 kg) and prior exposure to biologics therapy for psoriasis (yes/no).

In these studies, there was an initial 12-week placebo-controlled period where patients were randomized to Ilumya (including 100 mg and 200 mg at 0, 4 and every twelve weeks thereafter [Q12W]) or placebo. See study design in Table 3, below. Studies reSURFACE 1 and reSURFACE 2 assessed the changes from baseline at Week 12 in the two co-primary endpoints: 1) PASI 75 and 2) PGA of “0” (cleared) or “1” (minimal), with at least a 2-point improvement from baseline. Other evaluated outcomes in reSURFACE 1 and reSURFACE 2 included the proportion of patients who achieved PASI 90 and PASI 100. In the active comparator study (reSURFACE 2), patients were also randomized to receive etanercept 50 mg twice weekly for 12 weeks, and weekly thereafter up to 28 weeks. The total treatment period was 52 or 64 weeks.

Table 3 - Summary of the Clinical Study Design and Demographics for reSURFACE 1 and reSURFACE 2

Study	Trial design	Dosage, route of administration and duration	Study subjects	Mean age (range)	Sex
reSURFACE 1 (P010)	Phase 3 randomized, placebo-controlled, double-blind parallel study	TIL 100 mg or 200 mg, SC, at weeks 0, 4 and then every 12 weeks up to 64 weeks* or PBO SC at weeks 0 and 4; re-randomized to active treatment after 12 weeks**	772 (TIL 100 mg: 309; TIL 200 mg: 308; PBO: 155)	46.9 (18-82)	239 F (31%)/ 533 M (69%)
reSURFACE 2 (P011)	Phase 3 randomized, placebo- and active-controlled, double-blind, double-dummy parallel study	TIL 100 or 200 mg, SC, at weeks 0, 4 and then every 12 weeks up to 52 weeks* or PBO SC at weeks 0 and 4** or 50 mg ETN twice weekly for 12 weeks and once weekly up to 28 weeks***	1090 (TIL 100 mg: 307; TIL 200 mg: 314; PBO: 156; ETN: 313)	45.2 (19-81)	311 F (28.5%)/ 779 M (71.5%)

Etanercept: ETN, F: Female, M: Male, PBO: Placebo, SC: subcutaneous, TIL: Tildrakizumab
*TIL patients who did not achieve PASI 50 at Week 28 were discontinued from the trial.
**PBO patients were re-randomized 1:1 to receive TIL 100 mg or TIL 200 mg from Week 12 onward.
***ETN patients that were partial or non-responders at Week 28 were switched to TIL 200 mg.

Results obtained in reSURFACE 1 and reSURFACE 2 are presented in Table 4.

Patients in all treatment groups (reSURFACE 1 and reSURFACE 2) had a median baseline PASI score ranging from 17.7 to 18.4. The baseline PGA score was marked or severe in 33.4% of patients. Of all patients enrolled, 35.8% had received prior phototherapy, 41.1% had received prior conventional systemic therapy, 16.7% had received prior biologic therapy for the treatment of psoriasis, and 7.7% had received at least one anti-TNF alpha agent. A total of 15.4% of study patients had a history of psoriatic arthritis.

Table 4 - Efficacy Results at Week 12 in Adults with Plaque Psoriasis in Studies reSURFACE 1 and reSURFACE 2

	reSURFACE 1		reSURFACE 2		
	Ilumya 100 mg	**Placebo**	**Ilumya 100 mg**	**Etanercept**	**Placebo**
Number of patients*	309	154	307	313	156
Efficacy at Week 12 [a]					
PASI 75, n (%)	197 (63.8)	9 (5.8)	188 (61.2)	151 (48.2)	9 (5.8)
Difference versus placebo, % (95% CI) [b]	58.0 (51.0, 64.1) [c]		55.5 (48.3, 61.8) [c]		
Difference versus etanercept, % (95% CI) [b]	NA		13.1 (5.3, 20.7) [d]		
PGA of "clear" or "minimal" with ≥2 grade improvement from baseline, n (%)	179 (57.9)	11 (7.1)	168 (54.7)	149 (47.6)	7 (4.5)
Difference versus placebo, % (95% CI) [b]	50.9 (43.6, 57.4) [c]		50.2 (43.2, 56.5) [c]		
Difference versus etanercept, % (95% CI) [b]	NA		7.3 (-0.5, 15.0)		
PASI 90, n (%)	107 (34.6)	4 (2.6)	119 (38.8)	67 (21.4)	2 (1.3)
Difference versus placebo, % (95% CI) [b]	32.1 (25.9, 38.0) [c]		37.5 (31.1, 43.4) [c]		
Difference versus etanercept, % (95% CI) [b]	NA		17.4 (10.3, 24.4)		
PASI 100, n (%)	43 (13.9)	2 (1.3)	38 (12.4)	15 (4.8)	0 (0)
Difference versus placebo, % (95% CI)	12.7 (8.0, 17.3) [c]		12.4 (8.5, 16.6) [c]		
Difference versus etanercept, % (95% CI) [b]	NA		7.6 (3.3, 12.3)		

CI: Confidence Interval, NA: Not applicable, PASI: Psoriasis Area and Severity Index, PGA: Physician Global Assessment.

[a] Non-responder imputation for missing data.

[b] Differences and CIs were calculated using Miettinen-Nurminen stratified by body weight (≤90 kg, >90 kg) and prior exposure to biologic therapy for psoriasis (yes/no)

[c] P<0.001. P values were calculated using the Cochran-Mantel-Haenszel test stratified by body weight (≤90 kg, >90 kg) and prior exposure to biologic therapy for psoriasis (yes/no). Within each study, the Type 1 error rate was controlled using a gate-keeping sequential testing procedure.

[d] P=0.001.

*Efficacy data based on full analysis set.

Maintenance of Response

To evaluate the maintenance and durability of response, patients originally randomized to Ilumya 100 mg who were responders at Week 28 (i.e. had achieved PASI 75 response, n=229/285) in reSURFACE 1 were re-randomized to an additional 36 weeks of either maintaining the same dose of Ilumya Q12W (every twelve weeks) or placebo. In reSURFACE

2, patients originally randomized to Ilumya 100 mg Q12W who were PASI 75 responders at Week 28 (n=216/290) were maintained at the same dose for an additional 24 weeks.

In reSURFACE 1, of the patients who were PASI 75 responders at Week 28 who continued with the same dose of Ilumya, 87.5% (98/112) of patients treated with Ilumya 100 mg maintained PASI 75 response at Week 64. Of the patients re-randomized to receive placebo, 49.0% (25/51) maintained a PASI 75 response at Week 64. In reSURFACE 2, 93.6% (191/204) of patients treated with Ilumya 100 mg who were PASI 75 responders at Week 28 maintained a PASI 75 response at Week 52.

Quality of Life/Patient reported Outcomes

In the Ilumya 100 mg groups in reSURFACE 1 and reSURFACE 2, the percentage of patients with Dermatology Life Quality Index (DLQI) of 0/1 (no impact on health-related quality of life) at Week 12 were 41.4% (126/304) and 40.2% (119/296) respectively and in the placebo groups, 5.3% and 8%, respectively. A DLQI score of 0/1 was achieved at Week 52 by 63.7% (72/113) and 68.8% (141/205) of patients who were PASI 75 responders at Week 28 and received continuous treatment with 100 mg Ilumya in reSURFACE 1 and reSURFACE 2 respectively.

Retreatment after Relapse

In reSURFACE 1, there were 114 patients, who had achieved PASI 75 response at Week 28 who were re-randomized to placebo. There were 54.4% (n=62/114) of these patients who experienced relapse (defined as a reduction in maximum PASI response by 50%). Thirty-five (35) patients were restarted on 100 mg Ilumya upon relapse. After a minimum of 12 weeks from re-initiation of therapy, 85.7% (n=30/35) had regained a PASI 75 response at Week 64.

Psoriasis of the scalp

In a multicenter, randomized, double-blind, placebo-controlled trial (TILD-18-20), 231 subjects with moderate to severe psoriasis of the scalp (Investigator Global Assessment [IGA] Scalp score of 3 or 4) were treated subcutaneously with Ilumya 100 mg (n=117) or placebo (n=114) at Week 0 and 4 and every 12 weeks thereafter. The majority of the subjects were White (78.9%) and males (60.2%). The median age was 43 years (range: 18-79), and 54.4% subjects had body weight ≤ 90 kg. Baseline characteristics showed that the majority of the subjects did not have prior TNF-alpha inhibitor use (90.6%). The majority of the subjects had moderate disease burden based on IGA Mod 2011 (Scalp) and IGA Mod 2011 (whole-body). Subjects had a affected scalp surface area (SSA) of 50% (median), a median PASI score of 16.7, and PGA score of 3 (“moderate”) or 4 (“severe”) in 87.1% and 12.3% of all subjects, respectively. Overall, the demographic and baseline characteristics were balanced between the two arms.

The primary endpoint was the proportion of subjects with IGA mod 2011 (scalp) score of “clear” and “almost clear” with at least 2-point reduction from Baseline at Week 16.Other evaluated outcomes included the proportion of subjects achieving a) PSSI 90 at Week 16; b) PSSI 90 at Week 12; and c) IGA mod (2011) scalp score of “clear” or “almost clear” with at least 2-point reduction from Baseline at Week 12.

The efficacy results are presented in Table 6.

Table 6 – Efficacy Results for Primary and Key Secondary Endpoints in Adults with Plaque Psoriasis of the Scalp in Study TILD-18-20 (mITT, NRI)

	Ilumya 100 mg	**Placebo**
Number of patients	89	82
Primary Endpoint		
IGA Mod 2011 (Scalp) Response Rate for score 0 or 1 (clear or almost clear) at **Week 16**; n (%)	44 (49.4)	6 (7.3)
Difference versus placebo, % (95% CI)	40 (28.21, 51.75) [a]	
p-value	<0.00001 [b]	
Key Secondary Endpoints		
PSSI-90 Response Rate at **Week 16**; n (%)	54 (60.7)	4 (4.9)
Difference versus placebo, % (95% CI)	53.0 (42.32, 63.66) [a]	
p-value	<0.00001 [b]	
PSSI-90 Response Rate at **Week 12**; n (%)	43 (48.3)	2 (2.4)
Difference versus placebo, % (95% CI)	44.2 (33.26, 55.10) [a]	
p-value	<0.00001 [b]	
IGA Mod 2011 (Scalp) Response Rate for score 0 or 1 (clear or almost clear) at **Week 12**; n (%)	41 (46.1)	4 (4.9)
Difference versus placebo, % (95% CI)	39.0 (27.62, 50.44) [a]	
p-value	<0.00001 [b]	

Note: CI = confidence interval; IGA = Investigator Global Assessment; mITT = Modified Intent-To-Treat Set; NRI = Non-responder imputation; PSSI = Psoriasis Scalp Severity index.
[a] Response Rate Difference and CI are calculated using Miettinen-Nurminen, stratified by body weight (≤90kg, >90kg) and prior exposure to TNF-alpha inhibitors (yes/no).
[b] p-value is calculated using the Cochran-Mantel-Haenszel (CMH) test stratified by body weight (≤90kg, >90kg) and prior exposure to TNF-alpha inhibitors (yes/no). P-value is not adjusted for multiplicity.

A significantly higher proportion of subjects in the tildrakizumab 100 mg arm (49.4%) than in the placebo arm (7.3%) achieved IGA mod 2011 (scalp) response at Week 16. Statistically significant results (p <0.00001) were also observed for the key secondary efficacy endpoints (PSSI 90 score, and IGA (scalp only) response), demonstrating superiority of Ilumya over placebo in the treatment of subjects with moderate to severe plaque psoriasis of the scalp.

16 NON-CLINICAL TOXICOLOGY

General Toxicology

In the 3- and 9-month repeat dose toxicity studies in cynomolgus monkeys, tildrakizumab was well-tolerated at doses up to 140 mg/kg and 100 mg/kg administered subcutaneously once every 2 weeks, respectively. There were no tildrakizumab-related adverse effects observed, including no effects on cardiovascular, respiratory, and nervous system functions. At the no observed-adverse-effect level (NOAEL) of 140 and 100 mg/kg, bi- weekly in the 3- and 9-month repeat dose toxicity studies, the AUCs were approximately 155 and 90 times higher than the human exposure (305 mcg·day/mL) at maximum recommended human dose (MRHD) of 100 mg, derived from $AUC_{0\text{-}12week}$ using population pharmacokinetic model.

Carcinogenicity

Carcinogenicity studies have not been conducted with tildrakizumab.

Genotoxicity

Genotoxicity studies have not been conducted with tildrakizumab.

Reproductive and Developmental Toxicology

The effects of tildrakizumab were not directly assessed in dedicated animal fertility studies. However, no effects on fertility-related parameters, such as histopathology of reproductive organs, number or duration of menstrual cycle, or serum hormones levels (estradiol and progesterone) were observed in female cynomolgus monkeys that were administered tildrakizumab at doses up to 140 and 100 mg/kg by subcutaneous injections once every 2 weeks for 3- and 9-months, respectively (155 and 90 times the human exposure at the MRHD based on AUC). No adverse effects on male reproductive organs in terms of organ weights and histopathological findings were observed in a limited number of sexually mature males in the 3-month study (1/6 males, 2/6 males, 2/6 males in the low-, high (SC)-, and high (IV)-dose groups, respectively) and in the 9-month study (1/6 males in low-dose and no sexually mature males in the mid- and high-dose groups respectively). However, other male fertility-related endpoints, such as sperm analyses, were not evaluated in these studies.

An embryo-fetal development study was conducted with pregnant cynomolgus monkeys in which tildrakizumab was administered at doses up to 300 mg/kg (159 times the human exposure at the MRHD based on AUC) by subcutaneous injection once every 2 weeks during organogenesis (from gestation day 20 to 118). No malformations or embryo-fetal toxicity were observed at any dose.

In a pre- and postnatal development toxicity study, pregnant cynomolgus monkeys were administered subcutaneous doses of tildrakizumab once every 2 weeks at 10 or 100 mg/kg from gestational day 50 to parturition. No tildrakizumab-related increase in pregnancy loss was observed. Neonatal monkey deaths were observed, where maternal monkeys were given tildrakizumab (1/12 [8%] in the vehicle control group, 2/12 [17%] in the low-dose group and 4/14 [29%] in the high-dose group). AUC values at low and high dose were 6 and 59 times greater, respectively, than the human exposure levels at the MRHD. These neonatal deaths were attributed to maternal neglect, except for two neonates in the high-dose group, which died following viral infection. A drug related effect could not be ruled out. The clinical significance of these nonclinical findings is unknown. No tildrakizumab-related adverse effects on neurobehavioral or immunological development were observed in the surviving infants from birth through 6 months of age. A NOAEL of 10 mg/kg was determined based on an increase in postnatal deaths from infection observed at the highest dose.

Tildrakizumab was shown to distribute across the placental barrier; after repeated dosing to pregnant cynomolgus monkeys, serum concentrations were quantifiable in the fetus.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrIlumya®

Tildrakizumab injection

100 mg in 1 mL sterile solution (100 mg/mL) for subcutaneous injection

Read this carefully before you start taking Ilumya and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Ilumya.

What is Ilumya used for?

Ilumya is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches ("psoriatic lesions") that can appear anywhere on your body.

How does Ilumya work?

Ilumya contains the active substance tildrakizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation.

Using Ilumya should improve your skin clearance and reduce your symptoms of psoriasis such as itching, pain, stinging, burning and skin tightness.

What are the ingredients in Ilumya?

Medicinal ingredients: tildrakizumab

Non-medicinal ingredients: L-histidine (0.495 mg), histidine hydrochloride monohydrate (1.42 mg), polysorbate 80 (0.5 mg), sucrose (70.0 mg), and Sterile Water for Injection, USP.

Ilumya comes in the following dosage form:

- 1 mL (100 mg/mL) solution in a single-dose pre-filled syringe

Do not use Ilumya if:

- You are allergic to tildrakizumab or to any ingredients in Ilumya, including any non-medicinal ingredient, or component of the container. See **What are the ingredients in Ilumya?**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ilumya. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection or if you have an infection that does not go away or keeps coming back. Ilumya may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- think you have an infection or have symptoms of an infection such as
  - fever or flu-like symptoms
  - muscle aches
  - cough
  - shortness of breath
  - burning when you urinate or urinating more often than normal
  - blood in your phlegm (mucus)
  - weight loss
  - warm, red or painful skin or sores on your body different from your psoriasis
  - diarrhea or stomach pain
- have recently had a vaccination or if you are due to have a vaccination during treatment with Ilumya. You should not be given certain types of vaccines (live vaccines) while using Ilumya.

After starting Ilumya, call your healthcare provider right away if you have any of the symptoms of infection listed above.

- Do not use Ilumya if you have any symptoms of infection unless you are instructed to by your healthcare provider.

Other warnings you should know about:

Ilumya is not approved for children and adolescents under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if Ilumya can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Ilumya and for at least 4 months after the last Ilumya dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if Ilumya passes into breast milk. You and your doctor should decide if you should stop taking Ilumya or not breastfeed.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Ilumya

Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Ilumya is given by injection under your skin (subcutaneous injection).

You and your healthcare professional should decide if you should inject Ilumya yourself.

It is important not to try to inject yourself until you have been trained by your healthcare professional. A caregiver may also give you your Ilumya injection after proper training.

Before use, remove the carton from the refrigerator. Keep the pre-filled syringe inside the carton and allow it to reach room temperature by waiting for 30 minutes before injection.

Read the “Instructions for Use” document carefully before using the Ilumya pre-filled syringe.

Usual dose:

- The dose is 100 mg by a single subcutaneous injection.
- The first dose may be given by your healthcare provider.
- After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.

Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

You should not stop using Ilumya unless you think it is causing a severe side effect. Speak to your doctor as soon as possible if this happens.

Overdose:

If you have used more Ilumya than you should or the dose has been given sooner than prescribed, talk to your doctor.

If you think you, or a person you are caring for, have taken too much Ilumya, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of Ilumya, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. If you are not sure what to do, contact your healthcare professional.

What are possible side effects from using Ilumya?

As with all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the following side effects are mild to moderate and self-limiting. If any of these side effects becomes severe, tell your healthcare professional.

Very common: may affect more than 1 in 10 people

- Upper respiratory tract infection with symptoms such as sore throat and stuffy nose (nasopharyngitis)

Common: may affect up to 1 in 10 people

- Injection site reaction such as redness, pain, irritation, swelling, bruising, or itching at the site of injection
- Feeling tired
- Headache
- Diarrhea
- Pain in joints, arms, or legs

Uncommon: may affect up to 1 in 100 people

- Upset stomach or stomach pain
- Vomiting
- Impaired healing
- Muscle aches and pains
- Feeling of bodily discomfort, chills
- Skin infections/rashes
- Pink eye
- Ear infection
- Oral infection
- Swollen tongue or inflamed gums
- Dizziness
- Altered sense of taste or smell
- Burning when you urinate or urinating more often than normal

These are not all the possible side effects you may feel when taking Ilumya. If you experience any side effects not listed here, contact your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: *Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

Storage:

Ilumya should be stored refrigerated at 2°C to 8°C in the original carton to protect from light until the time of use. DO NOT FREEZE OR SHAKE. Ilumya can be transferred to room temperature storage (≤ 25°C) for up to 30 days in the original carton to protect from light until the time of use. Record the transfer date in the designated field provided on the carton. Once transferred to room temperature storage, do not place Ilumya back in the refrigerator. Use Ilumya within 30 days of transfer or by the expiry date printed on the carton, whichever occurs first. Do not store Ilumya above 25°C.

Ilumya must be kept out of reach and sight of children.

Discard any unused portion after injection.

Do not use Ilumya

- if you notice that the pre-filled syringe is damaged, or the seal is broken
- if the liquid in the pre-filled syringe is discoloured, cloudy or you can see other particles floating in it

If you want more information about Ilumya

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or by calling 1-844-924-0656.

This leaflet was prepared by Sun Pharmaceutical Industries Limited.

Last Revised June 27, 2025

INSTRUCTIONS FOR USE

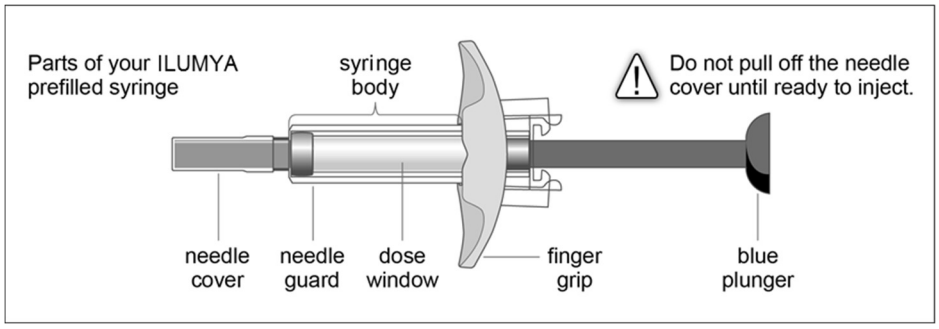
Ilumya®
(tildrakizumab injection)
Pre-filled syringe

Ilumya is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.

Ilumya is administered by subcutaneous injection. Full instructions for use are provided below.

After proper training in subcutaneous injection technique, you may self-inject Ilumya if your doctor determines that it is appropriate. Your doctor will ensure appropriate follow-up.

This is what Ilumya pre-filled syringes look like:



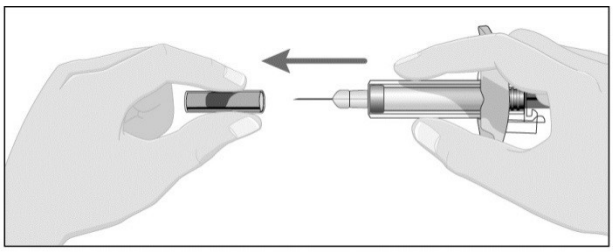
PREPARATION

- One syringe is needed for a 100 mg dose.
- Before injection, remove the carton pack containing the Ilumya pre-filled syringe from the refrigerator, and place on a clean and flat working surface.
- Leave the pre-filled syringe in the carton (with the lid closed) and let it sit at room temperature to warm for 30 minutes.

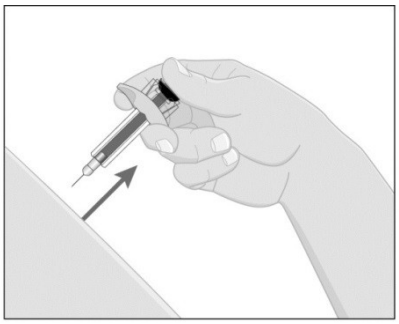
- Remove the pre-filled syringe from the carton when ready to inject.
  - DO NOT pull off the needle cover until you are ready to inject.
  - Check the expiration date on the carton and pre-filled syringe and discard if the date has passed.
- Inspect Ilumya visually for particulate matter and discoloration prior to administration.
  - Ilumya is a clear to slightly opalescent, colorless to slightly yellow solution.
  - DO NOT use if the liquid contains visible particles or the syringe is damaged. Air bubbles may be present; there is no need to remove them.
- Choose an injection site with clear skin and easy access such as abdomen, thighs or upper arm.
  - DO NOT administer within 5 cm around the navel or where the skin is tender, bruised, abnormally red or affected by psoriasis.
  - DO NOT inject into scars, stretch marks, or blood vessels.

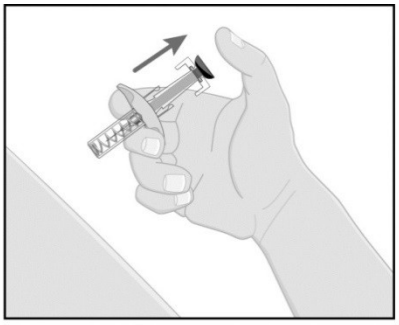
INJECTION

- While holding the body of the syringe, remove the needle cover as shown and discard. Do not twist.



- Inject Ilumya subcutaneously as recommended:
  - The recommended dose is 100 mg at regular scheduled intervals: weeks 0, 4 and every 12 weeks thereafter.
  - Your doctor will decide for how long you need Ilumya.
- Press down the blue plunger until it can go no further. This activates the safety mechanism that will ensure full retraction of the needle after the injection is given. A complete dose is administered if the blue plunger cannot go any further, and there are no spills.
- Remove the needle from the skin entirely before letting go of the blue plunger. After the blue plunger is released, the safely lock will draw the needle inside the needle guard.





- Dispose of used syringe in a sharp's disposal container right away after use.

Special precautions for storage

Ilumya should be stored refrigerated at 2°C to 8°C in the original carton to protect from light until the time of use. DO NOT FREEZE OR SHAKE. Ilumya can be transferred to room temperature storage (≤ 25°C) for up to 30 days in the original carton to protect from light until the time of use. Record the transfer date in the designated field provided on the carton. Once transferred to room temperature storage, do not place Ilumya back in the refrigerator. Use Ilumya within 30 days of transfer or by the expiry date printed on the carton, whichever occurs first. Do not store Ilumya above 25°C.

Ilumya must be kept out of the reach of children and sight of children.

Discard any unused portion after injection.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrIlumya®

Tildrakizumab injection

100 mg in 1 mL sterile solution (100 mg/mL) for subcutaneous injection

Read this carefully before you start taking Ilumya and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Ilumya.

What is Ilumya used for?

Ilumya is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches ("psoriatic lesions") that can appear anywhere on your body.

How does Ilumya work?

Ilumya contains the active substance tildrakizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation.

Using Ilumya should improve your skin clearance and reduce your symptoms of psoriasis such as itching, pain, stinging, burning and skin tightness.

What are the ingredients in Ilumya?

Medicinal ingredients: tildrakizumab

Non-medicinal ingredients: L-histidine (0.495 mg), histidine hydrochloride monohydrate (1.42 mg), polysorbate 80 (0.5 mg), sucrose (70.0 mg), and Sterile Water for Injection, USP.

Ilumya comes in the following dosage form:

- 1 mL (100 mg/mL) solution in a single-dose pre-filled pen

Do not use Ilumya if:

- You are allergic to tildrakizumab or to any ingredients in Ilumya, including any non-medicinal ingredient, or component of the container. See **What are the ingredients in Ilumya?**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ilumya. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection or if you have an infection that does not go away or keeps coming back. Ilumya may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- think you have an infection or have symptoms of an infection such as
  - fever or flu-like symptoms
  - muscle aches
  - cough
  - shortness of breath
  - burning when you urinate or urinating more often than normal
  - blood in your phlegm (mucus)
  - weight loss
  - warm, red or painful skin or sores on your body different from your psoriasis
  - diarrhea or stomach pain
- have recently had a vaccination or if you are due to have a vaccination during treatment with Ilumya. You should not be given certain types of vaccines (live vaccines) while using Ilumya.

After starting Ilumya, call your healthcare provider right away if you have any of the symptoms of infection listed above.

- Do not use Ilumya if you have any symptoms of infection unless you are instructed to by your healthcare provider.

Other warnings you should know about:

Ilumya is not approved for children and adolescents under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if Ilumya can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Ilumya and for at least 4 months after the last Ilumya dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if Ilumya passes into breast milk. You and your doctor should decide if you should stop taking Ilumya or not breastfeed.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Ilumya

Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Ilumya is given by injection under your skin (subcutaneous injection).

You and your healthcare professional should decide if you should inject Ilumya yourself.

It is important not to try to inject yourself until you have been trained by your healthcare professional. A caregiver may also give you your Ilumya injection after proper training.

Before use, remove the carton from the refrigerator. Keep the pre-filled pen inside the carton and allow it to reach room temperature by waiting for 30 minutes before injection.

Read the “Instructions for Use” document carefully before using the Ilumya pre-filled pen.

Usual dose:

- The dose is 100 mg by a single subcutaneous injection.
- The first dose may be given by your healthcare provider.
- After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.

Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

You should not stop using Ilumya unless you think it is causing a severe side effect. Speak to your doctor as soon as possible if this happens.

Overdose:

If you have used more Ilumya than you should or the dose has been given sooner than prescribed, talk to your doctor.

If you think you, or a person you are caring for, have taken too much Ilumya, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of Ilumya, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. If you are not sure what to do, contact your healthcare professional.

What are possible side effects from using Ilumya?

As with all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the following side effects are mild to moderate and self-limiting. If any of these side effects become severe, tell your healthcare professional.

Very common: may affect more than 1 in 10 people

- Upper respiratory tract infection with symptoms such as sore throat and stuffy nose (nasopharyngitis)

Common: may affect up to 1 in 10 people

- Injection site reaction such as redness, pain, irritation, swelling, bruising, or itching at the site of injection
- Feeling tired
- Headache
- Diarrhea
- Pain in joints, arms, or legs

Uncommon: may affect up to 1 in 100 people

- Upset stomach or stomach pain
- Vomiting
- Impaired healing
- Muscle aches and pains
- Feeling of bodily discomfort, chills
- Skin infections/rashes
- Pink eye
- Ear infection
- Oral infection
- Swollen tongue or inflamed gums
- Dizziness
- Altered sense of taste or smell
- Burning when you urinate or urinating more often than normal

These are not all the possible side effects you may feel when taking Ilumya. If you experience any side effects not listed here, contact your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: *Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

Storage:

Ilumya should be stored refrigerated at 2°C to 8°C in the original carton to protect from light until the time of use. DO NOT FREEZE OR SHAKE. Ilumya can be transferred to room temperature storage (≤ 25°C) for up to 30 days in the original carton to protect from light until the time of use. Record the transfer date in the designated field provided on the carton. Once transferred to room temperature storage, do not place Ilumya back in the refrigerator. Use Ilumya within 30 days of transfer or by the expiry date printed on the carton, whichever occurs first. Do not store Ilumya above 25°C.

Ilumya must be kept out of reach and sight of children.

Discard any unused portion after injection.

Do not use Ilumya

- if you notice that the grey needle cap on the pre-filled pen has been removed or damaged
- if the yellow plunger rod is visible in the window of the pre-filled pen
- if the liquid in the pre-filled is discoloured, cloudy or you can see other particles floating in it

If you want more information about Ilumya

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or by calling 1-844-924-0656.

This leaflet was prepared by Sun Pharmaceutical Industries Limited.

Last Revised June 27, 2025

INSTRUCTIONS FOR USE

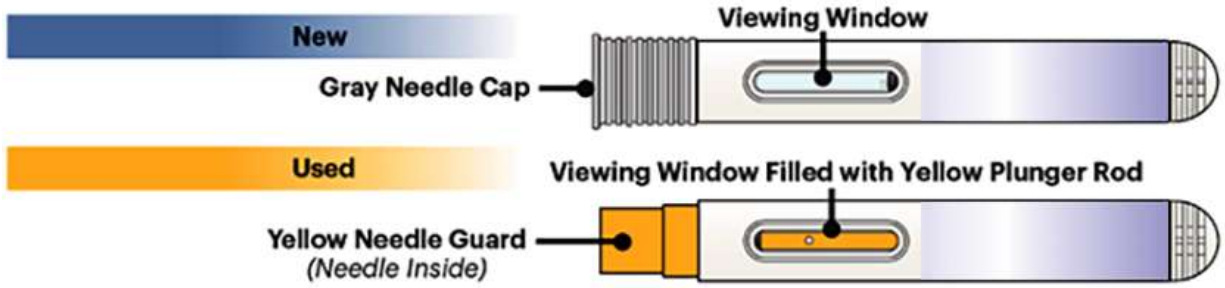
Ilumya®
(tildrakizumab injection)
Pre-filled pen

Ilumya is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.

Ilumya is administered by subcutaneous injection. Full instructions for use are provided below.

After proper training in subcutaneous injection technique, you may self-inject Ilumya if your doctor determines that it is appropriate. Your doctor will ensure appropriate follow-up.

This is what Ilumya pre-filled pens look like:



PREPARATION

- One Ilumya pre-filled pen is needed for a 100 mg dose.
- Before injection, remove the carton pack containing the Ilumya pre-filled pen from the refrigerator, and place on a clean and flat working surface.

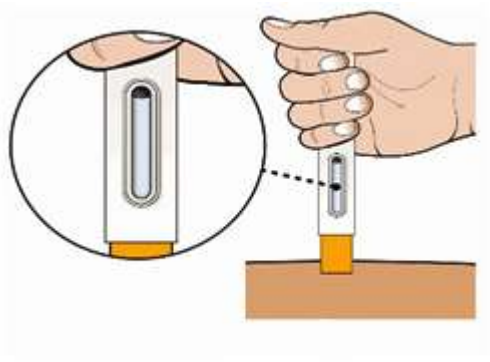
- Leave the pre-filled pen in the carton pack and let it sit at room temperature to warm for 30 minutes.
  - DO NOT shake the carton or pre-filled pen.
  - DO NOT warm the pre-filled pen any other way, such as in a microwave, hot water, or direct sunlight.
  - DO NOT use if the gray needle cap has been removed or damaged.
  - DO NOT use if the yellow plunger rod is visible in the window.
- Remove the pre-filled pen from the carton pack by holding it from the middle when ready to inject.
  - DO NOT remove the gray needle cap until you are ready to inject.
  - DO NOT put hand, fingers, or thumb over the yellow needle guard.
  - Check the expiration date on the carton and pre-filled pen and discard if the date has passed.
- Inspect Ilumya visually through the viewing window for particulate matter and discoloration prior to administration.
  - Ilumya is a clear to slightly opalescent, colorless to slightly yellow solution.
  - DO NOT use if the liquid looks cloudy, discolored, or has foreign particles. Air bubbles may be present; there is no need to remove them.
- **Wash your hands** well with soap and water and then dry your hands.

- Choose an injection site with clear skin and easy access such as front of thigh, abdomen or back of upper arm.
  - DO NOT administer within 5 cm around the navel, or where the skin is tender, bruised, hard, abnormally red or affected by psoriasis.
  - DO NOT inject into scars, stretch marks, or blood vessels.
- Clean the injection site by wiping the skin with an alcohol wipe and allow the skin to air dry.
  - DO NOT blow on skin to dry.
  - DO NOT touch the injection site after it has been cleaned.

INJECTION

- Remove the gray needle cap from the pre-filled pen by pulling it straight off. It may take some force to remove the cap.
  - DO NOT touch the yellow needle guard.
  - DO NOT put the gray needle cap back onto the pre-filled pen.
  - DO NOT twist or bend the needle guard while removing it, as this may damage the needle.

- Hold the pre-filled pen with the viewing window **facing you**.
- Stretch the skin and place the pre-filled pen straight on the cleaned injection site with the yellow needle guard flat on the skin.



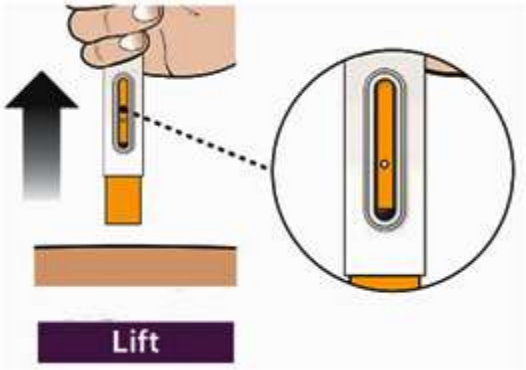
- Inject Ilumya subcutaneously as recommended:
  - The recommended dose is 100 mg at regular scheduled intervals: weeks 0, 4 and every 12 weeks thereafter.
  - Your doctor will decide for how long you need Ilumya.

To start the injection:

- Press and hold the pre-filled pen all the way down against the skin. This will make the yellow needle guard slide up into the pre-filled pen.

- You will hear the 1st “Click” that lets you know the injection has started.
- A 2nd, “Click” lets you know the injection is almost complete. Hold the pre-filled pen for a total of 15 seconds after the injection has started to make sure that all the medicine has been injected. Count slowly to fifteen seconds and ensure the second “click” has been heard.

- **Check the viewing window.** The color of the viewing window will be filled yellow.
- Lift the pre-filled pen straight up from the skin.
  - DO NOT lift the pre-filled pen away from the skin until the injection is complete. Doing so may result in an incomplete injection.
  - DO NOT use the pre-filled pen if the yellow needle guard does not slide into the pre-filled pen; immediately discard it into a sharp’s disposal container.



Special precautions for storage

The Ilumya pre-filled pen should be refrigerated at 2°C to 8°C and stored in the original carton to protect from light until the time of use. DO NOT FREEZE OR SHAKE. Ilumya can be transferred to room temperature storage (≤ 25°C) for up to 30 days in the original carton to protect from light until the time of use. Record the transfer date in the designated field provided on the carton. Once transferred to room temperature storage, do not place Ilumya back in the refrigerator. Use Ilumya within 30 days of transfer or by the expiry date printed on the carton, whichever occurs first. DO NOT store Ilumya above 25°C.

Keep the Ilumya pre-filled pen and gray cap (when removed) out of the reach of children and pets.

Discard any unused portion after injection.