

Psoriasis

and Biologic Treatments



**Choose the best treatment
to regain your quality of life.**

Edition 5



PSORIASIS, What is this disease?

Psoriasis is a common disease, that affects up to 4% of the population. It usually begins in one's twenties but can start at any age. Psoriasis is caused by a disorder of the immune system: it constantly stimulates the growth of the skin, as if it wants to be fixed, but it is not damaged. The result is the formation of red and thick plaques, with abundant dead scaly skin. Dysregulation of the immune system affects the skin but can also affect the tendons and joints. One in three people with psoriasis have associated arthritis. In people with psoriasis, the risk of diabetes, obesity, high cholesterol, hypertension, depression is higher.

There are different types of psoriasis. This document addresses the most common form, plaque psoriasis.

Plaque psoriasis evolves slowly. It often starts on the scalp, elbows or knees. It can remain stable or spread. It often causes itch and discomfort. The appearance of these lesions affects quality of life: the visible plaques may elicit inappropriate and/or hurtful questions. Is it contagious? Is it from being dirty or unhygienic? These questions demonstrate the general lack of understanding of this disease. You know that the disease is not contagious and that it has no link with hygiene but incessant questions and strange looks may become embarrassing. This may lead to a loss of self-esteem, withdrawal from social activities, restriction of clothing and entertainment options, and more.

What treatments are available?

Different psoriasis treatments are available; the choice of treatment depends largely on the severity of the disease.

Creams, gels, lotions, solutions, foams, ointments:

- topical steroids (products with cortisone)
- tar (Targel, liquor carbonis detergens)
- vitamin A derivatives (Tazorac)
- vitamin D derivatives (Dovonex, Silkis)
- topical immunomodulators: Tacrolimus (Protopic), Pimecrolimus (Elidel)
- compounded formulas (Dovobet = steroid + vitamin D derivative) (Diprosalic= steroid + salicylic acid).

Phototherapy (treatment with ultraviolet rays)

- Ultraviolet B rays (Broad & Narrow Band-UVB)
- PUVA (oral or topical Psoralen followed by controlled UVA rays)

Traditional Oral Treatments

- Acitretin (Soriatane)
- Methotrexate (also available by injection)
- Cyclosporine (Neoral)

Advanced Oral Treatments

- Apremilast (Otezla)

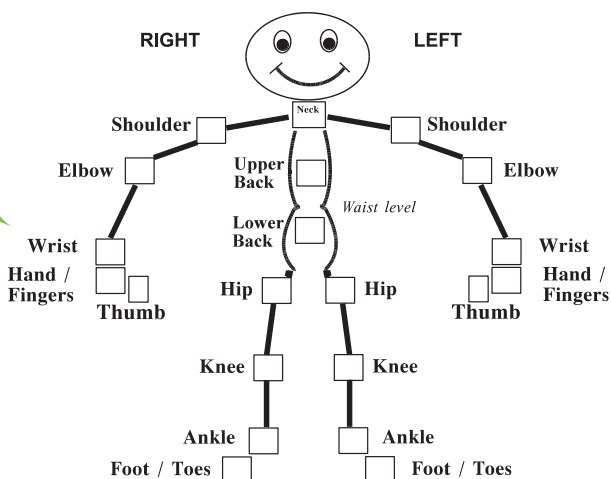
Biologic Treatments

- Infliximab (Remicade): intravenous infusions
- Etanercept (Enbrel): subcutaneous injections
- Adalimumab (Humira): subcutaneous injections
- Certolizumab (Cimzia): subcutaneous injections
- Secukinumab (Cosentyx): subcutaneous injections
- Ixekizumab (Taltz): subcutaneous injections
- Brodalumab (Siliq): subcutaneous injections
- Ustekinumab (Stelara): subcutaneous injections
- Guselkumab (Tremfya): subcutaneous injections
- Risankizumab (Skyrizi) : subcutaneous injections

Screening Questionnaire for Psoriatic Arthritis

Have you ever had a swollen joint (or joints)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has a doctor ever told you that you have arthritis?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Do your finger nails or toe nails have holes or pits?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Have you had pain in your heel?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Have you had a finger or toe that was completely swollen and painful for no apparent reason?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

In the drawing below, please tick the joints that have caused you discomfort (i.e. stiff, swollen or painful joints).



Phototherapy (treatment with ultraviolet rays)

Phototherapy using a specific band of UVB rays (narrowband UVB, NB-UVB) is often an effective treatment for psoriasis. It usually requires three visits a week to a therapy centre (in the hospital or in some dermatology clinics). The number of treatments to achieve satisfactory results varies from one person to the next. When psoriasis control is achieved, maintenance treatment is often required. The risks of this treatment are the same as those related to sun exposure, though to a lesser degree.

PUVA, which is the oral administration of a psoralen (photosensitizer) followed by exposure to UVA rays, is a very effective treatment. However, it is rarely used because of the risk of developing skin cancer, especially if the number of exposures exceeds 200. The use of PUVA is almost exclusively reserved for topical application to small affected areas of the skin (hands and feet, for example). PUVA is not widely available.

Traditional Oral Treatments

Acitretin (Soriatane)

Acitretin is a derivative of vitamin A. It is administered as oral tablets (10 mg and 25 mg). It has average effectiveness in psoriasis, but some people get great results. Side effects are rare at low doses. When the dosage is increased, dry lips, dry inner nostrils, fatigue, among other side effects can occur. Moreover, cholesterol and triglycerides (fat in the blood) may increase and should be monitored by blood tests. Rarely, liver enzymes may also increase. Acitretin is contra-indicated in women of childbearing age without the use of highly effective contraceptive methods as it is teratogenic.

Methotrexate

Methotrexate is an anti-inflammatory drug used for decades to treat psoriasis and arthritis. It is effective in about 40% of cases of psoriasis. It is prescribed in tablets or injections taken once per week. The results are apparent after about 8 weeks of treatment. The dose used for the treatment of psoriasis range from 10 to 25 mg per week.

Side effects vary from person to person. The risk of side effects is higher in obese and/or diabetic people and especially among those who regularly consume of alcohol (beer, wine, liquor). Short-term side effects primarily include changes in blood counts, or gastrointestinal symptoms (nausea, upset stomach). Side effects from prolonged use include possible liver damage but this occurs almost only in people regularly consuming alcohol. A supplement of folic acid (vitamin B9) is highly recommended to reduce side effects. Blood tests at regular intervals are essential for adequate monitoring. This drug is also contraindicated when pregnancy is being actively considered.

Cyclosporine (Neoral)

Cyclosporine is highly effective for the treatment of psoriasis. Over 70% of people will have a great response. It is dosed according to body weight: 2.5 mg to 5 mg per kg per day, divided into two doses every 12 hours. The response is rapid: psoriasis decreases in less than 8 weeks. The short term side effect is an increase in blood pressure: it must be closely monitored every week. An elevation of lipids (fats in the blood) is also monitored by regular blood tests.

Other rare events are transient headaches and muscle cramps. In the long term (over 2 years of continuous use), this drug can cause kidney failure. Regular bloodwork is essential to check kidney function. Cyclosporine is prescribed for a maximum of 2 years, except in special situations. Side effects vary depending on the required dose and duration of treatment: the higher the dose and longer the period of use, the greater the risk to the kidneys.

Advanced Oral Treatments

Apremilast (Otezla)

Apremilast (Otezla) has been available since 2014. Otezla is an oral tablet. About a third of psoriasis patients have a satisfactory response to a dose of 30 mg twice daily. The dose should be reduced in people with kidney failure. The most common side effects are transient nausea and mild diarrhea in the first weeks. Transient headaches are possible. Weight loss can occur during long-term treatment. However, the majority of individuals have no side effects.

Biologic Treatments

The arrival of biologic therapies in the early 2000s was a revolution in the treatment of psoriasis and psoriatic arthritis. Biologics are targeted treatments, remarkably effective and with minimal risk when used properly.

There are 2 main classes of biological agents against psoriasis: TNF inhibitors and interleukin inhibitors. The TNF inhibitors are: etanercept, adalimumab, infliximab and certolizumab (and golimumab for psoriatic arthritis). The interleukin inhibitors are: ustekinumab (inhibitor of interleukin 12 and 23), secukinumab, ixekizumab and brodalumab (inhibitors of interleukin 17), guselkumab and risankizumab (inhibitors of interleukin 23).

Biologics, however, cost considerably more than traditional treatments (phototherapy, methotrexate, cyclosporine, acitretin). They are covered by most drug plans, including provincial formularies, but only under certain conditions: the disease must be of significant severity, should have a significant impact on quality of life, and the patient must have failed to respond adequately or have contraindications to traditional treatments. The severity of disease is measured by the specialist and the impact of the disease is estimated by a questionnaire, the DLQI. The DLQI is attached to this document.

Biologic agents:

INTRAVENOUS

This type of drug is administered at an infusion centre.

In addition to monitoring your vital signs (*temperature, blood pressure, heart rate*), a health care provider will ask about your health and ensure that there are no contra-indications to treatment.

Only one drug is available for the intravenous treatment of psoriasis: Remicade

Remicade 5 mg/kg – anti-TNF



Frequency: Infusion at baseline and at weeks 2 and 6, then every 8 weeks. Your doctor may adjust the frequency if there is inadequate psoriasis control.

Duration: The infusion lasts at least two hours (can be reduced to 1 hour in certain circumstances)

Medications given by subcutaneous injection (syringe or auto-injector)

Enbrel 50 mg – anti-TNF



Availability: auto-injector pen (Sure-Click) or pre-filled syringe.

Frequency: One injection of 50 mg twice a week for 12 weeks, then one or two injections a week depending on your results.

Humira 40 mg – anti-TNF



Availability: auto-injector (PEN) or pre-filled syringe.

Frequency: Two injections on Day 1, then one injection a week later, then one injection every two weeks.

Cimzia 200 mg – anti-TNF



Availability: auto-injector or pre-filled syringe.

Frequency: Two injections (2 x 200 mg) on Day 1 and every other week thereafter.

Cosentyx 150 mg – *anti-interleukin 17A*



Availability: auto-injector or pre-filled syringe.

Frequency:

Two injections of 150 mg at weeks 0, 1, 2, 3 and 4 then two injections every 4 weeks.

Taltz 80 mg – *anti-interleukin 17A*



Availability: auto-injector or pre-filled syringe.

Frequency: Two injections of 80 mg on Day 1 then one injection at weeks 2, 4, 6, 8, 10, and 12 then every 4 weeks.

Siliq 210 mg – *receptor blocker of interleukin 17A, C, E, F*



Availability: pre-filled syringes.

Frequency: One injection on Day 1 and week 1, then every other week.

Stelara 45 mg or 90 mg – *anti-interleukin 12/23*



Availability: pre-filled syringe.

Frequency: One injection on Day 1, then at week 4, then every 12 weeks. The frequency may eventually be adjusted if required and approved.

Tremfya 100 mg – *anti-interleukin 23*



Availability: pre-filled syringe or patient controlled device.



Frequency: One injection on Day 1, then at week 4, then every 8 weeks.

Skyrizi 150 mg – *anti-interleukin 23*



Availability: pre-filled syringe.

Frequency: One injection on Day 1, then at week 4, then every 12 weeks.

Before starting treatment with a biologic agent (and other traditional treatments) some precautions are in order.

1. Ensure the absence of a latent or active tuberculosis infection. The doctor will ask questions and may order a **chest X-ray and a TB test**. The TB test may be a blood sample performed in specialized labs only (Quantiferon) or a skin test (PPD, performed at your health care provider's office).
2. Make sure your vaccinations are up to date, mainly for live attenuated vaccines. In adults, live vaccines include those against shingles (Zostavax), yellow fever (required if you plan travel in certain regions of Africa and Latin America), and the inhaled influenza (flu) vaccine (FluMist). **Vaccination with a live attenuated vaccine is contraindicated during treatment with biotherapy. The updated vaccination record is particularly important for children.** Note that killed vaccines (ie. injected vaccine against influenza, tetanus, pneumococcus, hepatitis A and B, Haemophilus influenza and the killed vaccine against shingles (Shingrix)) can be given at any time. However, it is preferable to receive all possible vaccinations **before** starting a biologic.
3. You should inform your doctor of any planned surgery to discuss **the risks and benefits associated with a biologic and surgery.**
4. Biologics directed **against TNF** should not be prescribed (or prescribed with great vigilance) if there is a personal or family history (father, mother, brother, sister) of symptoms or signs suggestive of **multiple sclerosis**. This warning is specific to **anti-TNFs** (Remicade, Enbrel, Humira, Cimzia, Simponi). **It does not apply to other biologics** (Stelara, Cosentyx, Taltz, Siliq, Tremfya, Skyrizi) nor to traditional treatments.
5. Severe heart failure is a contraindication to anti-TNFs (Remicade, Enbrel, Humira, Cimzia, Simponi).
6. Other contraindications that must be discussed with your doctor include: history of lymphoma, melanoma, severe or chronic infections, active hepatitis B.

Other information to know about Biologics

Biological treatments can affect your immune response. This is true for almost all systemic therapies. There may be an increased risk of infections, though the risk is low. However, when a significant infection occurs (fever, general malaise), stop treatment. Resume only after the infection has resolved. Note that the benefits of treatment far outweigh the risks and that infections are rare and treatable with common antibiotics.

It is important for you to submit an **updated list of all the medications you are taking** to your doctor, including supplements and, of course, treatments for your psoriasis.

The following are important events that may occur while on a biologic. Please take note of the suggested course of action:

Event	Remedy
Fever Serious Infection (pneumonia, wound infection, others) Treated with antibiotics	Stop biologic and go to emergency or see your family doctor or your dermatologist
Surgical Intervention Planning Pregnancy Travel	Consult your doctor

Patients' responsibilities when receiving oral medication or injections

By opting for systemic treatment, you have responsibilities, including:

- have an updated list of medications you take
- take your medication as prescribed
- undergo blood tests by the schedule discussed with your doctor
- store the drug as directed by the pharmacist and keep it out of the reach of children
- check the renewal date of your medicine
- make sure you have a follow up with your doctor

The prescriptions are not renewed automatically. In many clinics, appointments must be made at least 6 months in advance. A prescription renewal is not classified as an emergency.

DERMATOLOGY LIFE QUALITY INDEX

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick ✓ one box for each question.

- Over the last week, how itchy, sore, painful or stinging has your skin been?
 Very Much A Lot A little Not at all
- Over the last week, how embarrassed or self conscious have you been because of your skin?
 Very Much A Lot A little Not at all
- Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?
 Very Much A Lot A little Not at all Not applicable
- Over the last week, how much has your skin influenced the clothes you wear?
 Very Much A Lot A little Not at all Not applicable
- Over the last week, how much has your skin affected any social or leisure activities?
 Very Much A Lot A little Not at all Not applicable
- Over the last week, how much has your skin made it difficult for you to do any sport?
 Very Much A Lot A little Not at all Not applicable
- Over the last week, has your skin prevented you from working or studying?
 Yes NO Not applicable

If "No", over the last week how much has your skin been a problem at work or studying?
 A Lot A Little Not at all
- Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?
 Very Much A lot A little Not at all Not applicable
- Over the last week, how much has your skin caused any sexual difficulties?
 Very Much A Lot A little Not at all Not applicable
- Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?
 Very Much A Lot A little Not at all Not applicable

CHECKLIST (PRE-BIOLOGIC)

DOCTOR TO COMPLETE WITH THE PATIENT. Date: _____

Name:		
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	DOB:	
Age:	WT:	HT:
Age PSO started:	Family History of PSO? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> UNK	
BSA –Before Treatment: _____ %	BSA Presently: _____ %	
PASI –Before Treatment: _____	PASI Presently: _____	
Psoriasis sensitive areas: <input type="checkbox"/> Face <input type="checkbox"/> Hands <input type="checkbox"/> Feet <input type="checkbox"/> Genitals		
Nail Psoriasis: <input type="checkbox"/> Other: _____		

Treatments	YES	NO	If no, why:
Phototherapy	<input type="checkbox"/>	<input type="checkbox"/>	
Methotrexate	<input type="checkbox"/>	<input type="checkbox"/>	
Acitretin	<input type="checkbox"/>	<input type="checkbox"/>	
Cyclosporine	<input type="checkbox"/>	<input type="checkbox"/>	

Past medical history: Malignancy, chronic infections (TB, HIV, others)
Verified: <input type="checkbox"/> YES Comments: _____

Directed Physical Exam: Lymph Nodes & Skin
Done: <input type="checkbox"/> YES Comments: _____

Contra-indications	Verified: Yes	Notes:
CHF	<input type="checkbox"/>	
MS	<input type="checkbox"/>	
Cancer	<input type="checkbox"/>	
Chronic Infections	<input type="checkbox"/>	
Planning Pregnancy	<input type="checkbox"/>	
IBD	<input type="checkbox"/>	

Tests	Vérified: Yes	Notes:
PPD or Quantiferon	<input type="checkbox"/>	
CXR	<input type="checkbox"/>	
CBC	<input type="checkbox"/>	
Hepatitis serology B+C	<input type="checkbox"/>	
Creatinine	<input type="checkbox"/>	
ALT, Bilirubin	<input type="checkbox"/>	
HIV (if indicated)	<input type="checkbox"/>	

Tests for comorbidities (General Health): as needed

<i>Suggested:</i>	YES	NO	Notes:
Lipid Profile	<input type="checkbox"/>	<input type="checkbox"/>	
Fasting Glucose	<input type="checkbox"/>	<input type="checkbox"/>	

**CONCOMITANT MEDICATIONS
For PSORIASIS or PSORIATIC ARTHRITIS**

	YES	NO	
Methotrexate	<input type="checkbox"/>	<input type="checkbox"/>	Dose:
OTHERS?	<input type="checkbox"/>	<input type="checkbox"/>	Specify:

Other MEDICATIONS:

OPTIONAL

Vaccinations (For targeted populations)

Live Vaccine	YES	NO
Yellow Fever (Travelers to endemic areas)	<input type="checkbox"/>	<input type="checkbox"/>

**Vaccines that may be useful for anyone treated systemically
(Check local guidelines)**

Killed Vaccines	<i>Suggested:</i>	YES	NO	Comments
Pevnar and Pneumovax		<input type="checkbox"/>	<input type="checkbox"/>	
Haemophilus Influenzae (Hib)		<input type="checkbox"/>	<input type="checkbox"/>	
Flu Vaccine (Influenza)		<input type="checkbox"/>	<input type="checkbox"/>	
Twinrix (hepatitis A+B)		<input type="checkbox"/>	<input type="checkbox"/>	
Diphtheria-Tetanus		<input type="checkbox"/>	<input type="checkbox"/>	
Cholera		<input type="checkbox"/>	<input type="checkbox"/>	
Shingrix		<input type="checkbox"/>	<input type="checkbox"/>	

For children, an updated vaccination record is mandatory.

Introduction of biological agents is the most significant therapeutic development of recent years in the treatment of many diseases, including psoriasis.

Visit the following websites:

Canadian Dermatology Association

www.dermatology.ca

Canadian Association of psoriasis patients

www.skinpatientalliance.ca

Canadian psoriasis Network

www.canadianpsoriasisnetwork.com

Note: This document is a summary. It does not include all possible side effects, included in the monograph of each treatment.

Document created by Dr. Yves Poulin, MD.FRCPC. Dermatologist.

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Website, research center, Dr. Yves Poulin: **www.crdq.ca**

English Edition (translation and adaptation): R Vender, MD.FRCPC.

Director of Venderm Innovations in Psoriasis (ViP). **www.psoriasis.vip**

The following dermatologists actively participated in the update of this document: Dr. Danielle Brassard, Dr. Hélène Veillette, Dr. Pierre-Luc Dion, Dr. Marilyn Caron.

The following dermatologists also participated to the English translation: Dr. Michele Ramien, Dr. Mark Kirchhof.

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