

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TALTZ®

ixekizumab

Read this carefully before you start taking **TALTZ®** 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 **TALTZ**.

What is TALTZ used for?

Plaque Psoriasis

TALTZ is a prescription medicine used to treat adults and children 6 years or older with a skin condition called “plaque psoriasis”. Plaque psoriasis causes inflammation of the skin, appearing as raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body. TALTZ reduces the inflammation and other symptoms of the disease.

Psoriatic Arthritis

TALTZ is used to treat adults with active psoriatic arthritis and can be used alone or with another medicine called a conventional disease modifying anti-rheumatic drug (cDMARD), for example methotrexate. You may first be given other medicines for this disease. If you do not respond well enough to these medicines, you will be given TALTZ. Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. TALTZ reduces signs and symptoms of your arthritis and improves your psoriasis.

Ankylosing Spondylitis

TALTZ is used to treat a condition called ankylosing spondylitis. The condition is an inflammatory disease primarily affecting the spine, which causes inflammation of the spinal joints. TALTZ is used in adults with active ankylosing spondylitis. You may first be given other medicines for this disease. If you do not respond well enough to these medicines, you will be given TALTZ.

Non-Radiographic Axial Spondyloarthritis

TALTZ is used to treat adults with a type of arthritis of the back (spine) called non-radiographic axial spondyloarthritis. “Non-radiographic” means that you have symptoms of the disease but the damage cannot be seen on X-ray. You may first be given other medicines for this disease. If you do not respond well enough to these medicines, you will be given TALTZ to reduce the symptoms of your disease.

How does TALTZ work?

TALTZ contains the active substance ixekizumab. Ixekizumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body.

TALTZ belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by neutralizing the activity of a protein called IL-17A, which is present at increased levels in diseases such as plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis. By blocking IL-17A, TALTZ helps reduce the signs and symptoms of psoriasis such as itching, pain, and scaling; psoriatic arthritis such as painful and swollen joints; ankylosing spondylitis, and non-radiographic axial spondyloarthritis such as back pain and morning stiffness.

Using TALTZ will benefit you by leading to fast and sustained improvements of skin clearance and reducing your symptoms such as scaling, itching and pain. If you have any questions about how TALTZ works or why this medicine has been prescribed for you, ask your healthcare professional.

What are the ingredients in TALTZ?

Medicinal ingredients: ixekizumab

Non-medicinal ingredients: polysorbate 80, sucrose, and water for injection. Sodium hydroxide may have been added to adjust pH.

TALTZ comes in the following dosage forms:

- 80 mg solution for injection in prefilled autoinjector*
- 80 mg solution for injection in prefilled syringe*

*not all presentations may be marketed.

Do not use TALTZ if:

- you are allergic to ixekizumab or any of the other ingredients in TALTZ. See **What are the ingredients in TALTZ.**

If you think you may be allergic, ask your healthcare professional for advice before using TALTZ.

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

- currently have an infection or if you have long-term or repeated infections
- have tuberculosis or have been in close contact with someone with tuberculosis
- have inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- have recently had a vaccination or if you are due to have a vaccination during treatment with TALTZ

- are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light
- are pregnant, think that you may be pregnant or are planning to have a baby
- are breast-feeding or plan to breast-feed

Other warnings you should know about:

TALTZ may increase the risk of serious side effects, such as infections, allergic reactions, and development of new or worsening symptoms of inflammatory bowel disease. You must look out for signs of these conditions while you are taking TALTZ.

Stop using TALTZ and tell your healthcare professional or seek medical help immediately if you notice any signs indicating a possible serious infection, a serious allergic reaction, or new or worsening of inflammatory bowel disease.

Signs or symptoms of a potentially serious infection may include:

- fever, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in your phlegm (mucus)
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal

Signs or symptoms of a serious allergic reaction may include:

- feeling faint
- swelling of your face, eyelids, lips, mouth, tongue, or throat
- trouble breathing or throat tightness
- chest tightness
- skin rash

Signs or symptoms of inflammatory bowel disease may include:

- stomach pain
- diarrhea with or without blood
- weight loss

Children and adolescents

TALTZ is not recommended for children under 6 years of age with plaque psoriasis.

TALTZ is not recommended for children and adolescents (under 18 years of age) with the primary diagnosis of psoriatic arthritis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis.

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

Tell your doctor or pharmacist:

- If you (or your child) are taking, have recently taken or might take any other medicines.
- If you (or your child) have recently had or are going to have a vaccination. You should not receive certain types of vaccines (live vaccines) while using TALTZ.

How to take TALTZ:

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

Each prefilled autoinjector and each prefilled syringe contains one dose of TALTZ (80 mg). Each prefilled autoinjector and each prefilled syringe delivers only one dose.

TALTZ is given via injection under your skin (known as a subcutaneous injection). You and your healthcare professional should decide if you should inject TALTZ 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 TALTZ injection after proper training.

See the detailed Instructions for Use provided for information on how to prepare and inject a dose of TALTZ, and how to properly throw away used TALTZ prefilled autoinjectors and prefilled syringes.

Usual dose:

Your doctor will decide how much TALTZ you need and for how long.

Adult Plaque Psoriasis

- The initial dose is 160 mg (two injections) by subcutaneous injection.
- After the first dose you will receive further injections at Weeks 2, 4, 6, 8, 10, and 12. From Week 12, you will receive injections every 4 weeks. At each time point, after the initial dose, you will receive an 80 mg dose (one injection).

Pediatric Plaque Psoriasis

The usual dose given by subcutaneous injection for children 6 to less than 18 years of age is based on body weight.

Children's Body Weight	Starting Dose (Week 0)	Dose every 4 weeks (Q4W) Thereafter
Greater than 50 kg (i.e., 110 pounds)	160 mg (two 80 mg injections)	80 mg (one injection)
25 to 50 kg	80 mg (one injection)	40 mg (dose preparation required)
Less than 25 kg	40 mg (dose preparation required)	20 mg (dose preparation required)

If you weigh 50 kilograms (i.e., 110 pounds) or less, TALTZ doses of 20 mg and 40 mg must be prepared and given by a healthcare provider.

If you weigh more than 50 kilograms and if your doctor determines that it is appropriate, you or a responsible caregiver may be able to administer TALTZ at home after proper training in injection technique.

Psoriatic Arthritis

- The initial dose is 160 mg (two injections) by subcutaneous injection.
- After the first dose, you will receive 80 mg (one injection) every 4 weeks.
- For patients with psoriatic arthritis and with moderate-to-severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.
- For patients with psoriatic arthritis and with mild plaque psoriasis, use the dosing and administration recommendations for psoriatic arthritis.

Ankylosing Spondylitis

- You will receive 80 mg (one injection) by subcutaneous injection every 4 weeks.

Non-Radiographic Axial Spondyloarthritis

- You will receive 80 mg (one injection) by subcutaneous injection every 4 weeks.

TALTZ is for long-term treatment. Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

Overdose:

If you accidentally inject more TALTZ than you should or the dose has been administered sooner than according to your doctor's prescription, inform your healthcare professional.

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

Missed Dose:

If you have forgotten to inject a dose of TALTZ, inject the next dose as soon as you remember. Then talk to your healthcare professional to discuss when you should inject the next dose.

What are possible side effects from using TALTZ?

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

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

Some side effects are very common (may affect more than 1 in 10 people):

- upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis)
- injections site reactions (e.g. rash, pain, itch or swelling)

Some side effects are common (may affect up to 1 in 10 people):

- feeling sick to your stomach (nausea)
- athlete's foot (tinea pedis)
- sore throat
- diarrhea
- headache
- inflammation of the eye with redness, pain, and blurred vision (iritocyclitis)

Some side effects are uncommon (may affect up to 1 in 100 people):

- oral thrush (oral candidiasis)
- fever, flu-like symptoms
- runny nose
- hives
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- stomach pain, diarrhea with or without blood, weight loss (inflammatory bowel disease)
- eczema
- itching

These are not all the possible side effects you may have when taking TALTZ. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Serious allergic reactions (such as feeling faint; swelling of your face eyelids, lips, mouth, tongue, or throat; trouble breathing or throat tightness; chest tightness; or skin rash)		✓	✓

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

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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Storage:

Store in a refrigerator (2°C - 8°C). Do not freeze or shake. Do not use if TALTZ has been frozen. If needed, TALTZ may be left out of the refrigerator at a temperature up to 30°C (86°F) for up to 5 days. TALTZ should be discarded if not used within this 5-day period.

Store in the original packaging in order to protect from light.

Do not use TALTZ prefilled syringe or prefilled autoinjector:

- if you notice that it is damaged, or the medicine is cloudy, distinctly brown or yellow or has particles in it, or
- after the expiry date which is stated on the label and on the outer carton after “EXP”.

This medicine is for single use only. Ask your healthcare professional how to throw away medicines no longer required.

Keep out of reach and sight of children.

If you want more information about TALTZ:

- 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>); the manufacturer's website www.lilly.ca, or by calling 1-888-545-5972.
- The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.
- You may need to read this package insert again. Please do not throw it away until you have finished your medicine.

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