

Medication Guide
TALTZ® (tolts)
(ixekizumab)
injection, for subcutaneous use

What is the most important information I should know about TALTZ?

TALTZ is a medicine that affects your immune system. TALTZ may lower the ability of your immune system to fight infections and may increase your risk of infections, which can sometimes become serious.

- Your healthcare provider should check you for tuberculosis (TB) before you start treatment with TALTZ.
- Your healthcare provider may treat you with medicine for TB before you begin treatment with TALTZ if you have a past history of TB or have TB.
- Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TALTZ.

Before starting TALTZ, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have 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, 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

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

Do not use TALTZ if you have any symptoms of infection unless you are instructed to by your healthcare provider. See “**What are the possible side effects of TALTZ?**” for more information about side effects.

What is TALTZ?

TALTZ is a prescription medicine used to treat:

- people 6 years of age and older with moderate-to-severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults with active psoriatic arthritis. TALTZ can be used alone or with the medicine methotrexate.
- adults with active ankylosing spondylitis.
- adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

It is not known if TALTZ is safe and effective in children for conditions other than plaque psoriasis or in children under 6 years of age.

Do not use TALTZ if you have had a severe allergic reaction to ixekizumab or any of the other ingredients in TALTZ. See the end of this Medication Guide for a complete list of ingredients in TALTZ.

Before using TALTZ, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section “**What is the most important information I should know about TALTZ?**”
- have Crohn’s disease or ulcerative colitis
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TALTZ.
- are pregnant or plan to become pregnant. It is not known if TALTZ can harm your unborn baby.

Pregnancy Exposure Registry: There is a pregnancy registry to collect information about women who are exposed to TALTZ during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you become pregnant while taking TALTZ, you are encouraged to enroll in the pregnancy registry by calling 1-800-284-1695 or by visiting online at www.pregnancyregistry.lilly.com.

- are breastfeeding or plan to breastfeed. It is not known if TALTZ passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use TALTZ?

See the detailed “Instructions for Use” that comes with your TALTZ for information on how to prepare and inject a dose of TALTZ, and how to properly throw away (dispose of) used TALTZ autoinjectors and prefilled syringes.

- Use TALTZ exactly as prescribed by your or your child's healthcare provider.
- For children 6 to 17 years of age:
 - Your child's healthcare provider will decide which dose of TALTZ is right for your child and if you can give TALTZ to your child at home.
 - If your child's healthcare provider decides that you may give TALTZ injections at home, you should receive training on the right way to prepare and inject TALTZ. Do not try to give TALTZ to your child until you have been shown how to inject TALTZ.
 - Children should not inject themselves with TALTZ. You or an adult caregiver should prepare and give TALTZ injections to your child.
 - Children will be given a TALTZ injection every 4 weeks.
- For adults, if your healthcare provider decides that you or a caregiver may give your TALTZ injections at home, you should receive training on the right way to prepare and inject TALTZ. Do not try to inject TALTZ yourself, until you or your caregiver have been shown how to inject TALTZ.
- TALTZ comes in a single-dose autoinjector and single-dose prefilled syringes that you or your caregiver may use at home to give injections. Your or your child's healthcare provider will decide which type of TALTZ is best to use at home.
- TALTZ is given as an injection under the skin (subcutaneous injection), in the thighs or stomach area (abdomen) by you or a caregiver. A caregiver may also give the injection of TALTZ in the back of the arm.
- **Do not** give an injection in an area of the skin that is tender, bruised, red or hard, or in an area of skin that is affected by psoriasis.
- Each TALTZ injection should be given at a different site. **Do not** use the 1 inch area around your navel (belly button).

If you or your child forget to take a dose of TALTZ:

- Do not miss any doses of TALTZ unless your or your child's healthcare provider says it is okay. If you forget to take or give the TALTZ dose, inject a dose as soon as you remember. Then, take or give the next dose at the regular scheduled time.
- If you inject more TALTZ than prescribed, call your or your child's healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of TALTZ?

TALTZ may cause serious side effects, including:

- **See "What is the most important information I should know about TALTZ?"**
- **Serious allergic reactions. If you have a severe allergic reaction, do not give another injection of TALTZ.** Get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:

○ feel faint	○ trouble breathing or throat tightness
○ swelling of your face, eyelids, lips, mouth, tongue, or throat	○ chest tightness
	○ skin rash
- **Crohn's disease or ulcerative colitis (inflammatory bowel disease) can happen during treatment with TALTZ, including worsening symptoms.** Tell your healthcare provider if you have new or worsening symptoms of inflammatory bowel disease during treatment with TALTZ, including:
 - stomach (abdomen) pain
 - diarrhea with or without blood
 - weight loss

The most common side effects of TALTZ in adults and children include:

- | | |
|--------------------------------|---------------------|
| • injection site reactions | • nausea |
| • upper respiratory infections | • fungal infections |

These are not all of the possible side effects of TALTZ. Tell your healthcare provider about any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TALTZ?

- Protect TALTZ from light.
- Store TALTZ in the refrigerator between 36°F to 46°F (2°C to 8°C).
 - If needed, you or a caregiver may store TALTZ at room temperature up to 86°F (30°C) for up to 5 days in the original carton to protect from light. Once TALTZ has been stored at room temperature, do not return to the refrigerator. Throw away TALTZ if it is not used within 5 days at room temperature.
 - Record the date when TALTZ is first removed from the refrigerator in the spaces provided on the carton.

- For the 2 or 3 autoinjector pack, remove a single autoinjector at a time leaving the remaining autoinjector(s) in the original carton in the refrigerator. Make sure the unrefrigerated TALTZ is protected from light.
- Do not freeze TALTZ. Do not use if TALTZ has been frozen.
- Do not shake TALTZ.

Keep TALTZ and all medicines out of the reach of children.

General information about the safe and effective use of TALTZ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TALTZ for a condition for which it was not prescribed. Do not give TALTZ to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about TALTZ that is written for health professionals.

What are the ingredients in TALTZ?

Active ingredient: ixekizumab

Inactive ingredients: Polysorbate 80, Sucrose, and Water for Injection. Sodium Hydroxide may have been added to adjust pH.

Not made with natural rubber latex.

For more information about TALTZ, call 1-800-545-5979 (1-800-LillyRx) or go to the following website: www.taltz.com.

TALTZ® (ixekizumab) injection is a registered trademark of Eli Lilly and Company.

Eli Lilly and Company Indianapolis, IN 46285, USA, US License Number 1891

Copyright © 2016, 2024, Eli Lilly and Company. All rights reserved.

TAL-0010-MG-20240202