taltz®
(ixekizumab)
injection
80 mg/mL

Taltz dosing

Taltz is **indicated** for:

- Patients as young as 6 with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

Taltz is **contraindicated** in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

Please see additional Important Safety Information on page 6.
Please see full Prescribing Information and Medication Guide for Taltz.
See Instructions for Use included with the device.

Lilly

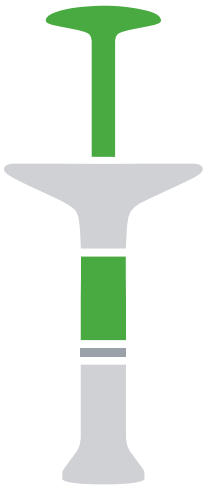
taltz® (ixekizumab) injection 80 mg/mL

Devices designed with patients' needs in mind[1]

TALTZ AUTOINJECTOR

or

TALTZ PREFILLED SYRINGE



Taltz 80 mg autoinjector and prefilled syringe are available for patients 6 years and older weighing >50 kg.* Caregivers may give injections after training in proper technique.

*Please see pediatric dosing regimen and preparation instructions for patients weighing ≤50 kg on page 5.

At first use, over 94% of adult patients with moderate to severe PsO agreed the Taltz autoinjector was "easy to use" and were confident in their ability to use it.

Trial A (N=204) was a phase 3, 12-week, multicenter, randomized, open-label trial in adult patients with moderate to severe plaque psoriasis. All patients received Taltz 80 mg every 2 weeks following a 160 mg starting dose. The primary objective was to evaluate the effect of the drug delivery device (prefilled syringe or autoinjector) on the pharmacokinetics of Taltz. Assessment of ease of administration was performed with the 12-item Subcutaneous Administration Assessment Questionnaire (SQAAQ) at weeks 0, 4, and 8.

Please see Instructions for Use included with the device.

SELECT IMPORTANT ADMINISTRATION INFORMATION

Adult patients may self-inject after training in subcutaneous injection technique. Administer each injection at a different anatomic location (such as upper arms, thighs, or any quadrant of abdomen) than the previous injection. Instruct patients to inject the full amount and not inject where the skin is tender, bruised, red, thick, or affected by psoriasis. For detailed administration instructions, please have patients read the Instructions for Use included with the device.

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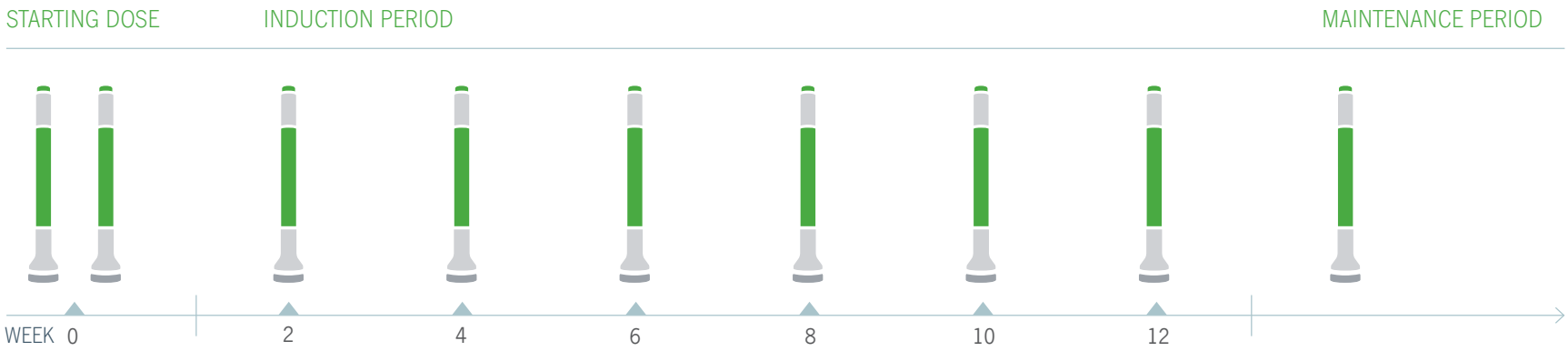
Taltz dosing for adults with PsO[2]

The dosing regimen is the same for adult patients with either moderate to severe PsO or PsA and coexistent moderate to severe PsO.



For adult patients who have PsA without coexistent moderate to severe PsO, the recommended dose is 160 mg (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks.

If patients forget to take their Taltz dose, instruct them to inject a dose as soon as they remember; then to take their next dose at the regularly scheduled time.

SELECT IMPORTANT ADMINISTRATION INFORMATION

Adult patients may self-inject after training in subcutaneous injection technique. Administer each injection at a different anatomic location (such as upper arms, thighs, or any quadrant of abdomen) than the previous injection. Instruct patients to inject the full amount and not inject where the skin is tender, bruised, red, thick, or affected by psoriasis. For detailed administration instructions, please have patients read the Instructions for Use included with the device.

SELECT IMPORTANT SAFETY INFORMATION: INFECTIONS

Taltz may increase the risk of infection. In clinical trials of adult patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis. Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

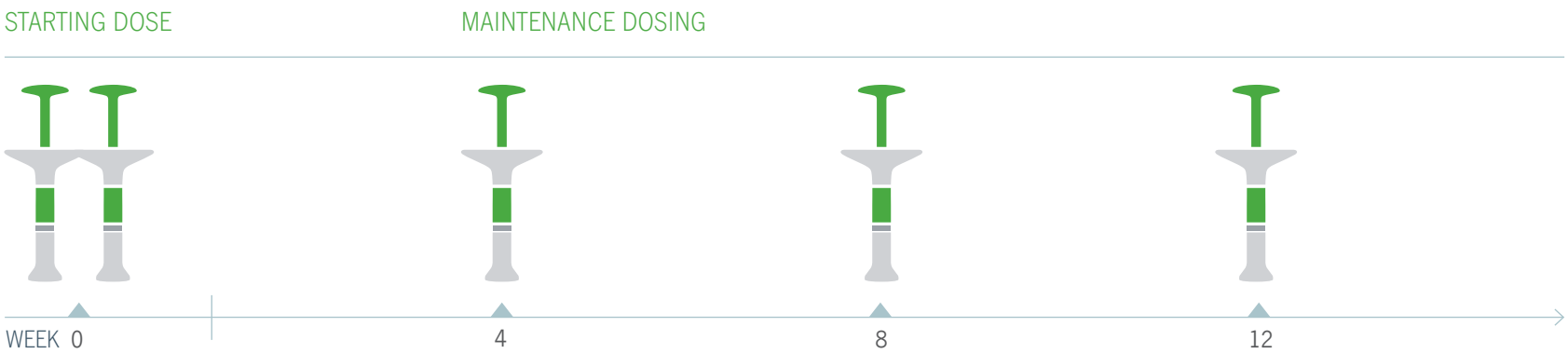
Please see additional Important Safety Information on page 6. Please see full Prescribing Information and Medication Guide for Taltz. See Instructions for Use included with the device.

taltz® (ixekizumab) injection 80 mg/mL

Taltz dosing for pediatric patients weighing >50 kg[2]

Taltz dosing for pediatric psoriasis is based on a patient's weight

For pediatric patients weighing >50 kg:



Starting dose:
2 injections
(80 mg each)

Maintenance Dose:
1 injection (80 mg) Q4W

Q4W=every 4 weeks.

If patients miss a dose, instruct them to receive a dose as soon as they remember, then to receive their next dose at their regularly scheduled time.

SELECT IMPORTANT ADMINISTRATION INFORMATION: PEDIATRIC PSORIASIS

Advise the patient and/or caregiver to read *Medication Guide* and *Instructions for Use* before the patient starts using Taltz, and each time the prescription is renewed, as there may be new information they need to know.

Taltz is intended for use under the guidance and supervision of a physician. Adult patients may self-inject or caregivers may give injections of 80 mg Taltz after training in subcutaneous injection technique using the autoinjector or prefilled syringe. Taltz doses of 20 mg or 40 mg must be prepared and administered by a qualified healthcare provider using aseptic technique.

Instructions on Self-Administration: Provide guidance to adult patients and caregivers on proper subcutaneous injection technique, including aseptic technique, and how to use the autoinjector or prefilled syringe correctly [see *Instructions for Use*]. Caregivers may give injections to pediatric patients weighing more than 50 kg using the autoinjector or prefilled syringe after training and demonstration of proper subcutaneous injection technique.

SELECT IMPORTANT SAFETY INFORMATION: PRE-TREATMENT EVALUATION FOR TUBERCULOSIS

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Closely monitor patients receiving Taltz for signs and symptoms of active TB during and after treatment.

Please see additional Important Safety Information on page 6. Please see full Prescribing Information and Medication Guide for Taltz. See Instructions for Use included with the device.

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Pediatric PsO dosing preparation for patients weighing ≤50 kg[2]

Taltz doses of 20 mg or 40 mg must be prepared and administered by a qualified healthcare provider.

Use only the commercial Taltz 80 mg/1 mL prefilled syringe when preparing the prescribed 20 mg and 40 mg pediatric doses.

PATIENT WEIGHT GROUP	STARTING DOSE (week 0)	MAINTENANCE DOSE (Q4W starting at week 4)
25-50 kg	**80 mg**	**40 mg**
<25 kg	**40 mg**	**20 mg**

Before injection, remove Taltz prefilled syringe from the refrigerator and allow Taltz to reach room temperature (30 minutes) without removing the needle cap. Keep away from direct heat or light. Inspect Taltz visually for particulate matter and discoloration prior to administration. Taltz is a clear and colorless to slightly yellow solution. Do not use if the liquid contains visible particles, is discolored, or cloudy (other than clear and colorless to slightly yellow). Administer each injection at a different anatomic location (such as upper arms, thighs, or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, indurated, or affected by psoriasis. Administration of Taltz in the upper, outer arm may be performed by a healthcare provider or a caregiver for pediatric patients >50 kg. Taltz does not contain preservatives; therefore, discard any unused product. If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regularly scheduled time. If necessary, the prepared Taltz dose may be stored at room temperature for up to 4 hours after initially puncturing the sterile vial.

NECESSARY SUPPLIES:

0.5 mL or 1 mL disposable syringe

Sterile needle for withdrawal

27-gauge sterile needle for administration

Sterile, clear glass vial

PREPARATION:

1

Expel the entire contents of the prefilled syringe into the sterile vial. DO NOT shake or swirl the vial. No other medications should be added to solutions containing Taltz.

2

Using the 0.5 mL or 1 mL disposable syringe and sterile needle, withdraw the prescribed dose from the vial (0.25 mL for 20 mg; 0.5 mL for 40 mg).

3

Remove the needle from the syringe and replace it with a 27-gauge needle prior to administering Taltz to the patient.

Storage: If necessary, the prepared Taltz dose may be stored at room temperature for up to 4 hours after initially puncturing the sterile vial. Taltz does not contain any preservatives; therefore, discard any unused product.

Questions? If you have questions or need assistance with supplies, please contact The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).

Please see Important Safety Information on page 6. Please see full Prescribing Information and Medication Guide for Taltz.
See Instructions for Use included with the device.

Important Safety Information

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CONTRAINDICATIONS

Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections

Taltz may increase the risk of infection. In clinical trials of adult patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis. Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Closely monitor patients receiving Taltz for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including angioedema and urticaria (each ≤0.1%), occurred in the Taltz group in clinical trials. Anaphylaxis, including cases leading to hospitalization, has been reported in post-marketing use with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease

Patients treated with Taltz may be at an increased risk of inflammatory bowel disease. In clinical trials, Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group than the placebo group. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease and if IBD occurs, discontinue Taltz and initiate appropriate medical management.

Immunizations

Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with Taltz.

ADVERSE REACTIONS

Most common adverse reactions (≥1%) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea, and tinea infections. Overall, the safety profiles observed in adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis were consistent with the safety profile in adult patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis and conjunctivitis, influenza, and urticaria in pediatric psoriasis.

Please see full Prescribing Information and Medication Guide for Taltz. See Instructions for Use included with the device.

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References: 1. Callis Duffin K, Bukhalo M, Bobonich MA, et al. Usability of a novel disposable autoinjector device for ixekizumab: results from a qualitative study and an open-label clinical trial, including patient-reported experience. *Med Devices (Auckl)*. 2016;9:361-369. **2.** Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.