Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
The dispensing of this medicine requires a doctor's prescription

Taltz 80 mg

Solution for injection in a pre-filled pen

Active ingredient and quantity in dosage units:
Each pre-filled pen contains 80 mg of ixekizumab in a 1 ml solution.

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional Information".
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is intended for adults over 18 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Taltz is intended for the treatment of the inflammatory diseases described below:

Plaque psoriasis
Taltz is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Psoriatic arthritis
Taltz, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies.

Ankylosing spondylitis (radiographic axial spondyloarthritis)
Taltz is indicated for the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy.

Non-radiographic axial spondyloarthritis
Taltz is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).

Therapeutic group: Immunosuppressants, interleukin inhibitors.

Ixekizumab belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by blocking the activity of a protein called IL-17A, which promotes psoriasis and inflammatory disease of the joints and the spine.

Using **Taltz** will benefit you by reducing the signs and symptoms of the disease, improving physical function (ability to do normal daily activities), and slowing down the damage to the joints.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if you:

- are allergic (hypersensitive) to ixekizumab or any of the other ingredients of this medicine (listed in section 6). If you are concerned that you may be allergic to this medicine, ask your doctor for advice before using **Taltz**.
- have an infection which your doctor thinks is serious (for example, active tuberculosis).

Special warnings regarding the use of this medicine

Before using Taltz, tell your doctor if:
- you currently have an infection or if you have long-term or repeated infections.
- you have an inflammatory disease affecting the gut named Crohn's disease.
- you have an inflammation of the large intestine named ulcerative colitis.
- you are receiving any other treatment for psoriasis (such as immunosuppressant or phototherapy with ultraviolet light) or for psoriatic arthritis.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)
Stop using **Taltz** and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhea, weight loss or blood in the stool (any signs of bowel problems).

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using **Taltz**.

Look out for infections and allergic reactions
Taltz can potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are using **Taltz**.

Stop using **Taltz** and tell your doctor or seek medical help immediately if you notice any signs of a serious infection or an allergic reaction. Such signs are listed under "Serious side effects" in section 4.

Interactions/Drug interactions
Tell your doctor, pharmacist or nurse if you are taking, or have recently taken, any other medicine, including nonprescription medicines and nutritional supplements. In particular, you must inform:
- if you have recently had or are due to have a vaccination. You should not be given certain types of vaccines while using **Taltz**.

Pregnancy, breastfeeding and fertility
If you are pregnant, think you may be pregnant, or are planning to become pregnant, ask your doctor for advice before using this medicine.
It is preferable to avoid the use of **Taltz** during pregnancy. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using **Taltz**, and for at least 10 weeks after the last **Taltz** dose.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. You and your doctor should decide if you can breastfeed or use **Taltz**. You should not do both.

Driving and using machines
Taltz is unlikely to influence your ability to drive and use machines.

Important information about some of this medicine's ingredients
This medicine contains less than 1 mmol sodium (23 mg) per 80 mg dose, i.e., essentially "sodium-free".

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Check with your doctor ,nurse or pharmacist if you are not sure.
The dosage and manner of treatment will be determined by the doctor only.

Taltz is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject **Taltz** yourself.

It is important not to try to inject yourself until you have been trained by your doctor or nurse. A caregiver may also give you your **Taltz** injection after proper training.

Use a reminder method such as notes in a calendar or diary to help you remember your next dose so that you avoid missing or repeating doses.

Taltz is intended for long-term treatment. Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect.

Each pen contains one dose of **Taltz** (80 mg). Each pen delivers only one dose. The pen must not be shaken.

Read the “Instructions for Use” for the pen carefully before using **Taltz**.

Acceptable dosage and duration of use
Your doctor will explain to you how much **Taltz** you need and for how long.

Plaque psoriasis
- The first dose is 160 mg (two pens with 80 mg each) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will use an 80 mg dose (one pen) at Weeks 2, 4, 6, 8, 10 and 12. From Week 12, you will use an 80 mg dose (one pen) every 4 weeks.

Psoriatic arthritis
For psoriatic arthritis patients who also have moderate to severe plaque psoriasis:
- The first dose is 160 mg (two pens with 80 mg each) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will use an 80 mg dose (one pen) at Weeks 2, 4, 6, 8, 10, and 12. From Week 12, you will use an 80 mg dose (one pen) every 4 weeks.

For other psoriatic arthritis patients
- The first dose is 160 mg (two pens with 80 mg each) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose you will use an 80 mg dose (one pen) every 4 weeks

Axial spondyloarthritis
The recommended dose is 160 mg (2 pens with 80 mg each) by subcutaneous injection at Week 0, followed by 80 mg (1 pen) every 4 weeks.

Do not exceed the recommended dose.

If you accidentally took a higher dose
If you have received more **Taltz** than you should or the dose has been given sooner than prescribed, inform your doctor.

If you have taken an overdose, or if a child has accidentally taken some medicine, go immediately to a hospital Emergency Room and bring the medicine package with you.

If you forgot to take Taltz
If you have forgotten to inject a dose of **Taltz**, talk to your doctor.
Persist with the treatment as recommended by the doctor.

If you stop using Taltz
Do not stop using **Taltz** without speaking to your doctor first. If you stop treatment, symptoms of psoriasis or psoriatic arthritis may come back.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, the use of **Taltz** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Serious side effects
Stop using **Taltz** and tell your doctor or seek medical help immediately if you get any of the following side effects. Your doctor will decide if and when you may restart the treatment:

Possible serious infection (may affect up to 1 in 100 people) - the signs may include:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Serious allergic reaction (may affect up to 1 in 1,000 people) - the signs may include:
- difficulty breathing or swallowing
- low blood pressure, which can cause dizziness or light-headedness
- swelling of the face, lips, tongue, or throat
- severe itching of the skin, with a red rash or raised bumps

Other side effects that have been reported:

Very common side effects (may affect more than 1 in 10 people):
- upper respiratory tract infections with symptoms such as sore throat and stuffy nose
- injection site reactions (e.g. red skin, pain)

Common side effects (may affect up to 1 in 10 people):
- nausea
- fungal infections such as athlete's foot
- pain in the back of the throat
- cold sores of mouth, skin and mucous membranes (herpes simplex, mucocutaneous)

Uncommon side effects (may affect up to 1 in 100 people):
- oral thrush (oral candidiasis)
- influenza
- runny nose
- bacterial skin infection
- hives
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- low blood platelet count (thrombocytopenia)
- eczema
- rash
- rapid swelling of the tissues of the neck, face, mouth or throat (angioedema)
- abdominal cramps and pain, diarrhea, weight loss or blood in the stool (signs of bowel problems)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment" that can be found on the Home Page of the Ministry of Health's website (www.health.gov.il), which refers to an online form for reporting side effects, or by entering the following link:
https://sideeffects.health.gov.il

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use this medicine after the expiry date (exp. date) which is stated on the pen label and on the outer carton. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C – 8°C). Do not freeze. Do not push to the back panel of the fridge. Do not shake.
The patient may store the product unrefrigerated for up to 5 days at a temperature below 30°C. Afterwards, the product must be discarded even if it hasn't been used.
Store in the original packaging in order to protect from light.
Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy, distinctly brown, or has particles in it.
This medicine is for single use only.

Do not throw away the medicine via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
Sodium chloride; sodium citrate dihydrate; citric acid anhydrous; polysorbate 80; water for injection.

What the medicine looks like and contents of the pack:
Taltz is a solution in a clear glass syringe. Its color may vary from colorless to slightly yellow.
The syringe is encased in a disposable, single-dose pen.
The package contains 1, 2, or 3 pre-filled pens.
Not all pack sizes may be marketed.

Registration holder and address: Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411

Manufacturer and address: Eli Lilly & Company Ltd., Indianapolis, Indiana, USA.

Revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157-73-34927-00.

I TALTPN S 07