TALTZ® (ixekizumab) PRESCRIBING INFORMATION

Presentation Ixekizumab solution for injection in a pre-filled syringe or pre-filled pen. Each single use pre-filled syringe and pre-filled pen contains 80 mg of ixekizumab in 1 mL solution. The solution is clear and colourless to slightly yellow. **Uses** Treatment of moderate to severe plaque psoriasis in • adults who are candidates for systemic therapy. • in children from the age of 6 years and with a body weight of at least 25 kg and adolescents who are candidates for systemic therapy. 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 (alone or in combination with methotrexate). Treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. Treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs). **Dosage and Administration** Posology *Plaque psoriasis in adults* Recommended dose: 160 mg by subcutaneous injection (two 80 mg injections) at week 0, followed by 80 mg (one injection) at weeks 2, 4, 6, 8, 10, and 12, then maintenance dosing of 80 mg (one injection) every 4 weeks. *Paediatric plaque psoriasis (age 6 years and above)* The recommended dose given by subcutaneous injection in children is based on the following weight categories: Greater than 50 kg: 160 mg (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks thereafter. 25-50kg: 80 mg at week 0, followed by 40 mg every 4 weeks thereafter. Ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional using the commercial Taltz 80 mg/1 ml prefilled syringe. For instructions on preparation of Taltz 40 mg, see SmPC. Doses less than 80 mg must be prepared by a healthcare professional. For children prescribed 80 mg, Taltz can be used directly from the prefilled syringe. Use the Taltz 80 mg pre-filled pen only in those children that require a dose of 80 mg and do not require dose preparation. Taltz is not recommended for use in children with a body weight below 25 kg. Paediatric body weights must be recorded and regularly re-checked prior to dosing. *Psoriatic arthritis* Recommended dose: 160 mg by subcutaneous injection (two 80 mg injections) at week 0, followed by 80 mg (one injection) every 4 weeks thereafter. For psoriatic arthritis patients with concomitant moderate to severe plaque psoriasis, the recommended dosing regimen is the same as for plaque psoriasis. *Axial spondyloarthritis (radiographic and non-radiographic)* Recommended dose: 160 mg (two 80 mg injections) by subcutaneous injection at week 0, followed by 80 mg every 4 weeks (see SmPC for further information). For all indications consideration should be given to discontinuing treatment in patients who have shown no response after 16 to 20 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 20 weeks. Special populations *Elderly:* No dose adjustment required. *Renal or hepatic impairment:* Taltz has not been studied in these patient populations. No dose recommendations can be made. *Paediatric plaque psoriasis (below a body weight of 25 kg and below the age of 6 years)* There is no relevant use of Taltz in children below a body weight of 25 kg and below the age of 6 years in the treatment of moderate to severe plaque psoriasis. *Paediatric population Paediatric psoriatic arthritis* The safety and efficacy of Taltz in children and adolescents aged 2 to less than 18 years in the treatment of psoriatic arthritis (a category of juvenile idiopathic arthritis) have not yet been established. No data are available. There is no relevant use of Taltz in children below 2 years for the indication of psoriatic arthritis Method of administration For subcutaneous injection. Injection sites may be alternated. If possible, areas of skin that show psoriasis should be avoided as injection sites. Must not be shaken. For instructions on preparation of the medicinal product before administration, refer to the SmPC. *Pre-filled syringe* Doses less than 80 mg which require dose preparation should only be administered by a healthcare professional. **Contra-indications** Serious hypersensitivity to the active substance or excipients. Clinically important active infections (e.g. active tuberculosis). **Warnings and Special Precautions** *Infections:* Treatment associated with an increased rate of infections such as upper respiratory tract infection, oral candidiasis, conjunctivitis, and tinea infections. Should be used with caution in patients with clinically important chronic infection or a history of recurrent infection. Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If an infection develops, patients should be carefully monitored and discontinued if the patient is not responding to standard therapy or if the infection becomes serious. Taltz should not be resumed until the infection resolves. Must not be given to patients with active tuberculosis (TB). Anti-TB therapy prior to initiation of Taltz in patients with latent TB should be considered. *Hypersensitivity:* Serious hypersensitivity reactions, including some cases of anaphylaxis, angioedema, urticaria and, rarely, late (10-14 days following injection) serious hypersensitivity reactions including widespread urticaria, dyspnea and high antibody titres have been reported. If a serious hypersensitivity reaction occurs, administration should be discontinued immediately and appropriate therapy initiated. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* Cases of new or exacerbations of inflammatory bowel disease have been reported (see SmPC). Ixekizumab is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, ixekizumab should be discontinued and appropriate medical management should be initiated. *Immunisations:* Should not be used with live vaccines. No data are available on the response to live vaccines: there are insufficient data on response to inactive vaccines. *Excipients:* This medicinal product contains less than 1 mmol sodium (23 mg) per 80 mg dose, that is to say essentially "sodium-free". (See SmPC for full information on excipients). **Interactions** Safety of Taltz in combination with other immunomodulatory agents or phototherapy has not been evaluated. In population pharmacokinetic analyses, clearance of ixekizumab was not affected by concomitant administration of oral corticosteroids, NSAIDs, sulfasalazine, or methotrexate. When Taltz was co-prescribed with substances metabolised by CYP3A4, CYP2C9, CYP2C19, CYP1A2 or CYP2D6 in patients with moderate to severe psoriasis no clinically significant impact on the pharmacokinetics of these substances was found. **Fertility, Pregnancy, and Lactation** *Women of childbearing potential:* Should use an effective method of contraception during treatment and for at least 10 weeks after treatment. *Pregnancy:* Recommended to avoid the use of Taltz during pregnancy. *Breast-feeding:* A decision should be made whether to discontinue breast-feeding or to discontinue Taltz. *Fertility:* The effect of ixekizumab on human fertility has not been evaluated. Animal studies do not indicate direct or indirect harmful effects with respect to fertility. **Effects on ability to drive and use machines** Taltz has no or negligible influence on the ability to drive and use machines. **Undesirable Effects** *Summary of the safety profile:* The most frequently reported adverse reactions were injection site reactions (15.5 %) and upper respiratory tract infections (16.4 %) (most frequently nasopharyngitis). *Injection site reactions:* The most frequent injection site reactions observed were erythema and pain. These reactions were predominantly mild to moderate in severity and did not lead to discontinuation of Taltz. *Infections:* In the placebo-controlled period of the phase III clinical studies in plaque psoriasis in adults, infections were reported in 27.2 % of patients treated with Taltz for up to 12 weeks compared with 22.9 % of patients treated with placebo. The majority of infections were non-serious and mild to moderate in severity, most of which did not necessitate treatment discontinuation. Serious infections occurred in 13 (0.6 %) of patients treated with Taltz and in 3 (0.4 %) of patients treated with placebo. Infection rates observed in psoriatic arthritis and axial spondyloarthritis clinical studies were similar to those observed in the plaque psoriasis studies with the exception of the frequencies of the adverse reactions of influenza and conjunctivitis which were common in patients with psoriatic arthritis. *Paediatric population:* The safety profile observed in children with plaque psoriasis is consistent with the safety profile in adult patients with plaque psoriasis with the exception of the frequencies of conjunctivitis, influenza, and urticaria which were common. Inflammatory bowel disease was also more frequent in paediatric patients, although it was still uncommon. *Very common (≥ 1/10):* Upper respiratory tract infection, injection site reactions. *Common (≥ 1/100 to < 1/10):* Tinea infection, herpes simplex (mucocutaneous), oropharyngeal pain, nausea. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom (Great Britain):*** *http://www.medicines.org.uk/emc/.* **Legal Category** POM **Marketing Authorisation Numbers and Holder** PLGB 55318/0001 PLGB 55318/0002 Eli Lilly and Company (Ireland) Limited, Dunderrow, Kinsale, Co. Cork, Ireland. **Cost (UK only)** £1,125 per pack of 1 pre-filled pen, £1,125 per pack of 1 pre-filled syringe, *An Irish price is available on request; please see section below for contact information.* **Date of Preparation or Last Review** October 2021 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Great Britain):** + 44-(0) 1256 315 000 E-mail: ukmedinfo@lilly.com Website: www.lilly.co.uk.

United Kingdom (Great Britain)

Adverse events and product complaints should be reported.
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Cork, Ireland **Cost (UK only)** £1,125 per pack of 1 pre-filled pen, £1,125 per pack of 1 pre-filled syringe, *An Irish price is available on request; please see section below for contact information.* **Date of Preparation or Last Review** August 2021 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Northern Ireland):** + 44-(0) 1256 315 000, **Ireland:** + 353-(0) 1 661 4377 E-mail: ukmedinfo@lilly.com Website: www.lilly.co.uk; www.lilly.ie.

Ireland and United Kingdom (Northern Ireland)

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