Olumiant® (baricitinib) PRESCRIBING INFORMATION

United Kingdom (Great Britain)

Presentation Olumiant 2 mg film-coated tablet contains 2 mg of baricitinib. Olumiant 2 mg tablet is a light pink, 9 x 7.5 mm oblong tablets, debossed with "Lilly" on one side and "2" on the other. Olumiant 4 mg film-coated tablet contains 4 mg of baricitinib. Olumiant 4 mg tablet is a medium pink, 8.5 mm round tablets, debossed with "Lilly" on one side and "4" on the other. **Uses** Rheumatoid arthritis Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate. Atopic dermatitis Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy. **Dosage and administration** Treatment should be initiated by physicians experienced in the diagnosis and treatment of the conditions for which Olumiant is indicated. Posology *Rheumatoid arthritis:* The recommended dose of baricitinib is 4 mg once daily. A dose of 2 mg once daily is appropriate for patients such as those aged ≥ 75 years and may be appropriate for patients with a history of chronic or recurrent infections. A dose of 2 mg once daily may also be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. *Atopic dermatitis:* The recommended dose of baricitinib is 4 mg once daily. A dose of 2 mg once daily is appropriate for patients such as those aged ≥ 75 years and may be appropriate for patients with a history of chronic or recurrent infections. A dose of 2 mg once daily should be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. Baricitinib can be used with or without topical corticosteroids. The efficacy of baricitinib can be enhanced when given with topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for sensitive areas only, such as the face, neck, intertriginous and genital areas. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 8 weeks of treatment. *Treatment initiation:* Treatment should not be initiated in patients with an absolute lymphocyte count (ALC) less than 0.5 x 10^9 cells/L, an absolute neutrophil count (ANC) less than 1 x 10^9 cells/L, or who have a haemoglobin value less than 8 g/dL. Treatment may be initiated once values have improved above these limits. *Renal impairment:* The recommended dose is 2 mg once daily in patients with creatinine clearance between 30 and 60 mL/min. Olumiant is not recommended for use in patients with creatinine clearance < 30 mL/min (see the SmPC for full information). *Hepatic impairment:* No dose adjustment is required in patients with mild or moderate hepatic impairment. Olumiant is not recommended for use in patients with severe hepatic impairment (see the SmPC for full information). *Co-administration with OAT3 inhibitors:* The recommended dose is 2 mg once daily in patients taking Organic Anion Transporter 3 (OAT3) inhibitors with a strong inhibition potential, such as probenecid (see the SmPC for full information). No clinical pharmacology study has been conducted with OAT3 inhibitors with less inhibition potential. The prodrug leflunomide rapidly converts to teriflunomide which is a weak OAT3 inhibitor and therefore may lead to an increase in baricitinib exposure. Since dedicated interaction studies have not been conducted, caution should be used when leflunomide or teriflunomide are given concomitantly with baricitinib (see the SmPC for full information on Interaction with other medicinal products and other forms of interaction). *Elderly:* Clinical experience in patients ≥ 75 years is very limited and in these patients a starting dose of 2 mg is appropriate. *Paediatric population:* The safety and efficacy of Olumiant in children and adolescents aged 0 to 18 years have not yet been established. No data are available. Method of administration Oral use: Baricitinib is to be taken once daily with or without food and may be taken at any time of the day. **Contra-indications** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. Pregnancy: Women of childbearing potential have to use effective contraception during and for at least 1 week after treatment. If a patient becomes pregnant while taking baricitinib the parents should be informed of the potential risk to the foetus. **Warnings and special precautions** Infections: Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo (see the SmPC for full information). In rheumatoid arthritis clinical studies, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment with baricitinib should be carefully considered prior to initiating therapy in patients with active, chronic or recurrent infections (see the SmPC for full information). If an infection develops, the patient should be monitored carefully and baricitinib therapy should be temporarily interrupted if the patient is not responding to standard therapy. Treatment should not be resumed until the infection resolves. *Tuberculosis:* Patients should be screened for tuberculosis (TB) before starting therapy. Baricitinib should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of treatment in patients with previously untreated latent TB. Haematological abnormalities: Absolute Neutrophil Count (ANC) < 1 x 10^9 cells/L and Absolute Lymphocyte Count (ALC) < 0.5 x 10^9 cells/L were reported in clinical trials. Haemoglobin < 8 g/dL was reported in rheumatoid arthritis clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1 x 10^9 cells/L, ALC < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management (see section 4.2 of the SmPC for further information). The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported. Viral reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies (see the SmPC for full information). In rheumatoid arthritis clinical studies, herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and conventional disease-modifying antirheumatic drugs (DMARDs). If a patient develops herpes zoster, treatment should be temporarily interrupted until the episode resolves. Vaccination: Use with live, attenuated vaccines during, or immediately prior to, baricitinib therapy is not recommended. Prior to initiating treatment, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Lipids: Dose dependent increases in blood lipid parameters were reported in patients treated with baricitinib (see the SmPC for full information). Elevations in low density lipoprotein (LDL) cholesterol decreased to pre-treatment levels in response to statin therapy. Lipid parameters should be assessed approximately 12 weeks following initiation of therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. Hepatic transaminase elevations: Dose dependent increases in blood alanine transaminase (ALT) and aspartate transaminase (AST) activity were reported in patients treated with baricitinib (see section 4.8). Increases in ALT and AST to ≥ 5 and ≥ 10 x upper limit of normal (ULN) were reported in clinical trials. In rheumatoid arthritis clinical studies, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy (see the SmPC for full information). If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, treatment should be temporarily interrupted until this diagnosis is excluded. Malignancy: The risk of malignancies including lymphoma is increased in patients with rheumatoid arthritis. Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. The clinical data are insufficient to assess the potential incidence of malignancies following exposure to baricitinib. Venous thromboembolism: Cases of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. Baricitinib should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation. If clinical features of DVT/PE occur, treatment should be discontinued and patients should be evaluated promptly, followed by appropriate treatment. Laboratory monitoring: Please refer to the SmPC for laboratory measures and monitoring guidance. Immunosuppressive medicinal products: Combination with biological DMARDs, biological immunomodulators or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. In rheumatoid arthritis, data concerning use of baricitinib with potent immunosuppressive medicinal products (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations (see the SmPC for full information). In atopic dermatitis, combination with ciclosporin or other potent immunosuppressants has not been studied and is not recommended (see the SmPC for full information). Hypersensitivity: In post-marketing experience, cases of hypersensitivity associated with baricitinib administration have been reported. If any serious allergic or anaphylactic reaction occurs, treatment should be discontinued immediately. Diverticulitis: Cases of diverticulitis and gastrointestinal perforation have been reported in clinical trials and from postmarketing sources (see the SmPC for full information). Baricitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medicinal products associated with an increased risk of diverticulitis: nonsteroidal anti-inflammatory drugs, corticosteroids, and opioids. Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of diverticulitis or gastrointestinal perforation. **Interactions** See the SmPC for full information on interaction with immunosuppressive medicinal products, potential for other medicinal products to affect the pharmacokinetics of baricitinib, and potential for baricitinib to affect the pharmacokinetics of other medicinal products. **Fertility, pregnancy, and lactation** *Pregnancy:* There are no adequate data from the use of baricitinib in pregnant women. Studies in animals have shown reproductive toxicity (see the SmPC for full information). Baricitinib was teratogenic in rats and rabbits. Baricitinib is contraindicated during pregnancy. *Breast-feeding:* It is unknown whether baricitinib/metabolites are excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of baricitinib in milk. A decision must be made whether to discontinue breast-feeding or to discontinue therapy. *Fertility:* The effect of baricitinib on human fertility has not been evaluated. Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis. **Effects on ability to drive and use machines** Baricitinib has no or negligible influence on the ability to drive and use machines. **Undesirable effects** *Summary of the safety profile:* The most commonly reported adverse reactions with baricitinib are increased LDL cholesterol (25.1 %), upper respiratory tract infections (16.7 %), headache (4.9 %), herpes simplex (3.7 %), and urinary tract infections (2.7 %). *Very common (≥ 1/10):* Upper respiratory tract infection, Hypercholesterolaemia, *Common (≥ 1/100 to < 1/10):* Herpes zoster, Herpes simplex, Gastroenteritis, Urinary tract infections, Pneumonia, Thrombocytosis > 600 x 10^9 cells/L, Headache, Nausea, Abdominal pain, ALT increased ≥ 3 x ULN, Rash, Acne, Creatine phosphokinase increased > 5 x ULN. *Uncommon (≥ 1/1,000 to < 1/100):* Neutropaenia < 1 x 10^9 cells/L, Swelling of the face, Hypertriglyceridaemia, Deep Vein Thrombosis, Pulmonary embolism, Diverticulitis, AST increased ≥ 3 x ULN, Urticaria, Weight increased. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom:*** *http://www.medicines.org.uk/emc/.* **Legal Category** POM **Marketing Authorisation Numbers and Holder** PLGB 14895/0255 PLGB 14895/0256 Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK only)** £805.56 per pack of 28 x 2 mg film-coated tablets, £805.56 per pack of 28 x 4 mg film-coated tablets, **Date of Preparation or Last Review:** May 2022 **Further information is available from** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK:** + 44-(0) 1256 315000 E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk

Adverse events and product complaints should be reported.
Reporting forms and information can be found at
UK: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events and product complaints should also be reported to Lilly: please call Lilly **UK** on **01256 315 000**.

Olumiant® (baricitinib) PRESCRIBING INFORMATION

Ireland and United Kingdom (Northern Ireland)

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If a patient becomes pregnant while taking baricitinib the parents should be informed of the potential risk to the foetus. **Warnings and special precautions** Infections: Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo (see the SmPC for full information). In rheumatoid arthritis clinical studies, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment with baricitinib should be carefully considered prior to initiating therapy in patients with active, chronic or recurrent infections (see the SmPC for full information). If an infection develops, the patient should be monitored carefully and baricitinib therapy should be temporarily interrupted if the patient is not responding to standard therapy. Treatment should not be resumed until the infection resolves. *Tuberculosis:* Patients should be screened for tuberculosis (TB) before starting therapy. Baricitinib should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of treatment in patients with previously untreated latent TB. Haematological abnormalities: Absolute Neutrophil Count (ANC) < 1 x 10^9 cells/L and Absolute Lymphocyte Count (ALC) < 0.5 x 10^9 cells/L were reported in clinical trials. Haemoglobin < 8 g/dL was reported in rheumatoid arthritis clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1 x 10^9 cells/L, ALC < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management (see section 4.2 of the SmPC for further information). The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported. Viral reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies (see the SmPC for full information). In rheumatoid arthritis clinical studies, herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and conventional disease-modifying antirheumatic drugs (DMARDs). If a patient develops herpes zoster, treatment should be temporarily interrupted until the episode resolves. Vaccination: Use with live, attenuated vaccines during, or immediately prior to, baricitinib therapy is not recommended. Prior to initiating treatment, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Lipids: Dose dependent increases in blood lipid parameters were reported in patients treated with baricitinib (see the SmPC for full information). Elevations in low density lipoprotein (LDL) cholesterol decreased to pre-treatment levels in response to statin therapy. Lipid parameters should be assessed approximately 12 weeks following initiation of therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. Hepatic transaminase elevations: Dose dependent increases in blood alanine transaminase (ALT) and aspartate transaminase (AST) activity were reported in patients treated with baricitinib (see section 4.8). Increases in ALT and AST to ≥ 5 and ≥ 10 x upper limit of normal (ULN) were reported in clinical trials. In rheumatoid arthritis clinical studies, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy (see the SmPC for full information). If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, treatment should be temporarily interrupted until this diagnosis is excluded. Malignancy: The risk of malignancies including lymphoma is increased in patients with rheumatoid arthritis. Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. The clinical data are insufficient to assess the potential incidence of malignancies following exposure to baricitinib. Venous thromboembolism: Cases of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. Baricitinib should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation. If clinical features of DVT/PE occur, treatment should be discontinued and patients should be evaluated promptly, followed by appropriate treatment. Laboratory monitoring: Please refer to the SmPC for laboratory measures and monitoring guidance. Immunosuppressive medicinal products: Combination with biological DMARDs, biological immunomodulators or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. In rheumatoid arthritis, data concerning use of baricitinib with potent immunosuppressive medicinal products (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations (see the SmPC for full information). In atopic dermatitis, combination with ciclosporin or other potent immunosuppressants has not been studied and is not recommended (see the SmPC for full information). Hypersensitivity: In post-marketing experience, cases of hypersensitivity associated with baricitinib administration have been reported. If any serious allergic or anaphylactic reaction occurs, treatment should be discontinued immediately. Diverticulitis: Cases of diverticulitis and gastrointestinal perforation have been reported in clinical trials and from postmarketing sources (see the SmPC for full information). Baricitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medicinal products associated with an increased risk of diverticulitis: nonsteroidal anti-inflammatory drugs, corticosteroids, and opioids. Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of diverticulitis or gastrointestinal perforation. **Interactions** See the SmPC for full information on interaction with immunosuppressive medicinal products, potential for other medicinal products to affect the pharmacokinetics of baricitinib, and potential for baricitinib to affect the pharmacokinetics of other medicinal products. **Fertility, pregnancy, and lactation** *Pregnancy:* There are no adequate data from the use of baricitinib in pregnant women. Studies in animals have shown reproductive toxicity (see the SmPC for full information). Baricitinib was teratogenic in rats and rabbits. Baricitinib is contraindicated during pregnancy. *Breast-feeding:* It is unknown whether baricitinib/metabolites are excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of baricitinib in milk. A decision must be made whether to discontinue breast-feeding or to discontinue therapy. *Fertility:* The effect of baricitinib on human fertility has not been evaluated. Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis. **Effects on ability to drive and use machines** Baricitinib has no or negligible influence on the ability to drive and use machines. **Undesirable effects** *Summary of the safety profile:* The most commonly reported adverse reactions with baricitinib are increased LDL cholesterol (25.1 %), upper respiratory tract infections (16.7 %), headache (4.9 %), herpes simplex (3.7 %), and urinary tract infections (2.7 %). *Very common (≥ 1/10):* Upper respiratory tract infection, Hypercholesterolaemia, *Common (≥ 1/100 to < 1/10):* Herpes zoster, Herpes simplex, Gastroenteritis, Urinary tract infections, Pneumonia, Thrombocytosis > 600 x 10^9 cells/L, Headache, Nausea, Abdominal pain, ALT increased ≥ 3 x ULN, Rash, Acne, Creatine phosphokinase increased > 5 x ULN. *Uncommon (≥ 1/1,000 to < 1/100):* Neutropaenia < 1 x 10^9 cells/L, Swelling of the face, Hypertriglyceridaemia, Deep Vein Thrombosis, Pulmonary embolism, Diverticulitis, AST increased ≥ 3 x ULN, Urticaria, Weight increased. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom (Northern Ireland)****: https://www.emcmedicines.com/en-GB/northernireland, or* ***Ireland****: http://www.medicines.ie/.* **Legal Category** POM **Marketing Authorisation Numbers and Holder** EU/1/16/1170/002, EU/1/16/1170/010, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK only)** £805.56 per pack of 28 x 2 mg film-coated tablets, £805.56 per pack of 28 x 4 mg film-coated tablets, *An Irish price is available on request; please see section below for contact information.* **Date of Preparation or Last Review:** November 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 315000, **Ireland:** + 353-(0) 1 661 4377, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk; www.lilly.ie.

Adverse events and product complaints should be reported.
Reporting forms and information can be found at
UK (Northern Ireland): www.mhra.gov.uk/yellowcard or search for
MHRA Yellow Card in the Google Play or Apple App Store,
or **Ireland: www.hpra.ie.**

Adverse events and product complaints should also be reported to Lilly:
please call Lilly **UK** on **01256 315 000**, or **Lilly Ireland** on **01 664 0446**.

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. 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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)

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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. 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Ireland and United Kingdom (Northern Ireland)

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