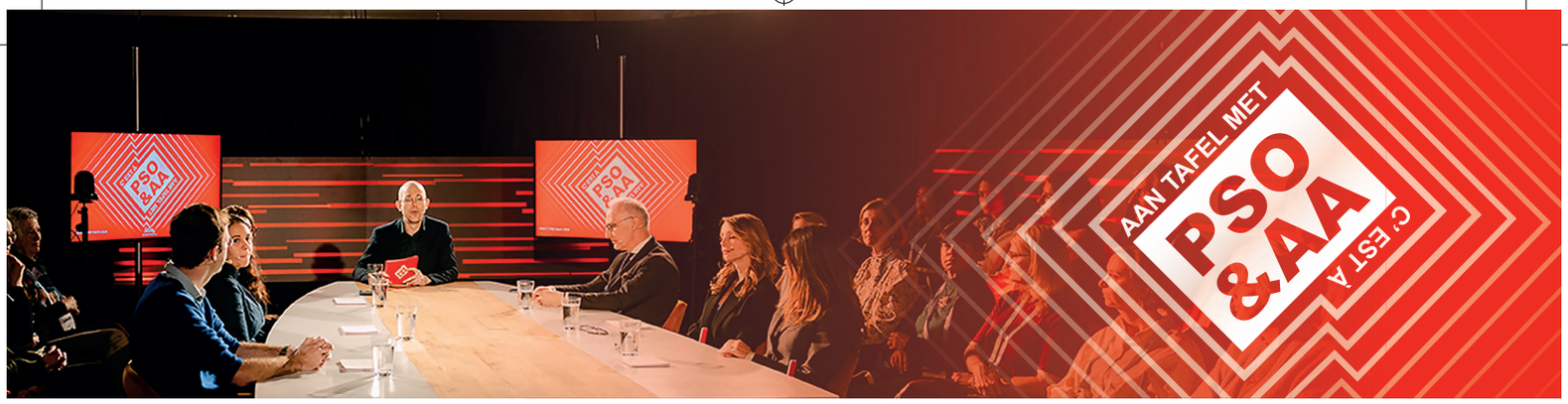

AAN TAFEL MET PSO EN AA:

Multidisciplinaire inzichten in psoriasis en alopecia areata

Tijdens de Belgian Dermatology Days 2026 organiseerde Eli Lilly onder de noemer 'Aan tafel met PsO en AA' een interactief rondetafelgesprek waarin actuele uitdagingen binnen de behandeling van psoriasis en alopecia areata centraal stonden. Onder moderatie van Dr. Sven Lanssens (Dermatologie Maldegem) bespraken Belgische en internationale dermatologen recente inzichten rond inflammatie, comorbiditeiten, therapierespons, patiëntverwachtingen en multidisciplinaire zorg. De sessie benadrukte hoe beide aandoeningen steeds meer worden beschouwd als complexe systemische ziekten waarbij een gepersonaliseerde aanpak essentieel is.

Obesitas als inflammatoire motor

Een eerste belangrijk thema was de relatie tussen obesitas en psoriasis. ***Dr. Annelies Stockman*** *(AZ Delta, Roeselare)* lichtte toe dat obesitas niet enkel frequent voorkomt bij psoriasis, maar ook actief bijdraagt aan de inflammatoire pathogenese van de aandoening. Adipeus weefsel fungeert immers als endocrien orgaan en produceert pro-inflammatoire cytokinen en hormonen zoals leptine, resistine, TNF-α en interleukine-6. Deze mediatoren stimuleren systemische inflammatie, insulineresistentie en vasculaire schade, wat het verhoogde cardiovasculaire risico bij patiënten met psoriasis mede verklaart. Daarnaast speelt IL-6 een belangrijke rol in de differentiatie van Th17-cellen, een centraal immunologisch mechanisme binnen psoriasis.[1,2]

Nieuwe gegevens bevestigen bovendien dat obesitas niet alleen geassocieerd is met een verhoogd risico op cardiometabole aandoeningen, maar ook met een grotere kans op het ontwikkelen van artritis psoriatica (PsA). Zowel een poster gepresenteerd op het EADV-congres als post-hocanalyses van de PSoHO-studie toonden aan dat patiënten met een BMI boven 30 en vroege tekenen van gewrichtsbetrokkenheid een verhoogd risico lopen op de ontwikkeling van PsA.[3,4] Tegen deze achtergrond groeit de aandacht voor therapeutische strategieën gericht op gewichtsreductie. Hierbij werd onder meer verwezen naar GLP-1-receptoragonisten zoals semaglutide en duale GLP-1/GIP-agonisten zoals tirzepatide. Volgens Dr. Stockman bieden deze behandelingen niet alleen metabole voordelen, maar mogelijk ook een gunstig effect op de inflammatoire activiteit van psoriasis en PsA.

Verminderde therapierespons bij obese patiënten

Aansluitend ging ***Prof. Dr. Julien Lambert*** *(UZA, Antwerpen)* dieper in op de impact van obesitas op de werkzaamheid van psoriasisbehandelingen. Op basis van een expertconsensusrapport werd benadrukt dat obese patiënten significant minder kans hebben om PASI-75 en PASI-90 te bereiken onder behandeling met biologische therapieën.[5] Deze verminderde respons werd waargenomen bij verschillende klassen biologics, waaronder TNF-α-, IL-17- en IL-23-remmers. Ook conventionele systemische therapieën zoals methotrexaat, ciclosporine en acitretine blijken minder werkzaam bij obese patiënten, terwijl obesitas tegelijk het risico op toxiciteit verhoogt. Zo werd gewezen op een verhoogde kans op hepatotoxiciteit bij methotrexaat en nefrotoxiciteit bij ciclosporine.[5]

Daarnaast ervaren patiënten met obesitas vaker praktische problemen bij topische behandelingen, onder meer door moeilijkheden bij applicatie en de nood aan grotere hoeveelheden product. Ook de drug survival van biologics blijkt lager bij obese patiënten. Volgens ***Prof. Lambert*** verdient het daarom aanbeveling om bij suboptimale respons eerst dosis- of intervalaanpassingen te overwegen alvorens over te schakelen naar een andere biologische therapie.

Scalp psoriasis: hoge ziektelast en therapeutische uitdagingen

Een volgend thema was psoriasis ter hoogte van de hoofdhuid, een lokalisatie die vaak gepaard gaat met een disproportioneel hoge impact op de levenskwaliteit. ***Prof. Dr. Farida Benhadou*** *(Hôpital Erasme, Brussels)* benadrukte dat scalp psoriasis niet alleen frequent voorkomt, maar ook therapeutisch bijzonder uitdagend is. Topische behandelingen blijven vaak moeilijk toepasbaar ter hoogte van de behaarde hoofdhuid, wat de therapietrouw negatief beïnvloedt. Hoewel systemische therapieën en biologics doorgaans effectiever zijn, blijven terugbetalingscriteria een belangrijke hinderpaal voor veel patiënten.[6]

Prof. Bianca Maria Piraccini *(University of Bologna)* wees erop dat patiënten met ernstige scalp psoriasis vaak onderbehandeld blijven ondanks de grote psychosociale impact van symptomen zoals zichtbare schilfering en jeuk. Daarnaast werd besproken dat scalpbetrokkenheid geassocieerd is met een verhoogd risico op PsA en dat het Koebnerfenomeen mogelijk bijdraagt aan persisterende inflammatie via activatie van aangeboren immuniteit en veranderingen in de huidmicrobiota. Vanuit die hypothese werd gesuggereerd dat snelwerkende IL-17-gerichte therapieën mogelijk voordelen bieden bij scalp psoriasis, gezien hun snelle symptoomcontrole en vroege verbetering van levenskwaliteit.[7,8]

Patiëntverwachtingen bij alopecia areata

Ook alopecia areata kwam uitgebreid aan bod tijdens het symposium. ***Dr. Marisa Mathieu*** *(CHU Brugmann, Brussel)* besprak de verwachtingen van patiënten met alopecia

areata, een aandoening die volgens haar nog te vaak als louter esthetisch wordt beschouwd. Patiënten hopen vooral op snelle en zichtbare haargroei, langdurige ziektecontrole en een voorspelbare behandelrespons. In de praktijk blijft deze respons echter moeilijk voorspelbaar, wat het belang van transparante communicatie onderstreept. Daarnaast hebben succesvolle behandelingen vaak een belangrijke psychologische impact, met verbetering van zelfbeeld, angst en levenskwaliteit. Verschillende studies tonen aan dat de ziektelast van alopecia areata vergelijkbaar is met of zelfs groter kan zijn dan die van psoriasis of atopische dermatitis.[9] Toch blijft de toegang tot JAK-inhibitoren sterk variëren binnen Europa.[10] België verkreeg recent terugbetaling voor baricitinib, terwijl ook terugbetaling van ritlecitinib werd aangevraagd.

Volgens ***Prof. Piraccini*** begint goede zorg bij alopecia areata met erkenning van de psychosociale impact van de aandoening en duidelijke communicatie over de mogelijke duur van de behandeling, de kans op herval en de verwachte tijd tot respons. Ook ***Prof. Reinhart Speeckaert*** *(UZ Gent)* benadrukte dat verwachtingsmanagement cruciaal is, aangezien patiënten vaak hopen op volledige en blijvende haargroei terwijl de behandelrespons in werkelijkheid zeer heterogeen verloopt.

Tijd tot respons op baricitinib blijft heterogeen

Prof. Speeckaert ging vervolgens dieper in op de tijd tot respons op baricitinib bij alopecia areata. Klinische studies tonen een uitgesproken variabiliteit in behandelrespons. Ongeveer één derde van de patiënten reageert reeds binnen de eerste drie maanden, terwijl een tweede groep geleidelijk reageert tussen drie en negen maanden. Daarnaast bestaan ook late responders die pas na negen tot twaalf maanden duidelijke haargroei ontwikkelen. Factoren zoals een kortere ziekteduur, minder uitgebreide ziekte en hogere doseringen baricitinib verhogen de kans op een vroege respons. Patiënten met alopecia totalis of een zeer lange ziekteduur hebben daarentegen vaker een minder gunstige prognose.[11]

Real-worlddata uit Spanje, China en Japan bevestigen deze heterogeniteit en tonen bovendien dat sommige patiënten zelfs na één jaar behandeling alsnog een significante respons kunnen ontwikkelen. Opvallend was dat vroege hergroei van wenkbrauwen en wimpers een predictor bleek van een latere respons op baricitinib.[12-14]

Praktische dilemma's en expertdiscussies

Tijdens de interactieve discussies werden daarnaast verschillende praktische dilemma's besproken. Er bestond consensus dat zogenaamde "high-impact areas" bij psoriasis, zoals hoofdhuid, nagels en genitaliën, vaak aanleiding geven tot behandelingsescalatie vanwege hun disproportionele impact op levenskwaliteit. Tegelijk werd benadrukt dat deze impact sterk patiëntafhankelijk is en dat de ervaren ziektelast belangrijker kan zijn dan de anatomische lokalisatie zelf. Daarom werd door het panel voorgesteld dat de term "treatment-resistant areas" mogelijk accurater is dan "high-impact areas".

Binnen alopecia areata waren de experten het unaniem eens dat vroege systemische therapie de kans op betekenisvolle haargroei verhoogt. Daarnaast werd uitgebreid stilgestaan bij de beperkingen van de klassieke SALT-score, die geen rekening houdt met verlies van wenkbrauwen en wimpers. Volgens de experten hebben deze regio's nochtans een grote functionele en psychosociale impact. Daarom ontwikkelde ***Prof. Speeckaert*** samen met collega's de VESALT-score, die deze regio's wel meeneemt.[15] Herstel van haargroei in deze regio's kan bovendien een vroege indicator zijn van een latere globale respons op therapie.[16]

Ook het veiligheidsprofiel van JAK-inhibitoren werd besproken. Volgens de experten mogen veiligheidsdata uit reumatoïde artritis niet zomaar geëxtrapoleerd worden naar alopecia areata, aangezien patiënten met alopecia areata doorgaans jonger en gezonder zijn en minder comorbiditeiten vertonen. Hierdoor lijkt het veiligheidsprofiel van baricitinib in de dagelijkse praktijk gunstiger dan in andere indicaties. Verder was er weinig steun voor de stelling dat patiënten die na twaalf maanden nog geen SALT ≤20 bereiken automatisch hun behandeling moeten stopzetten. Volgens de experten kunnen ook late responders nog significante verbetering vertonen, al vormen de huidige terugbetalingscriteria hierbij vaak een belangrijke beperking.[17]

Tot slot werd gediscussieerd over de rol van dermatologen in cardiovasculair risicomanagement bij psoriasis. Hoewel sommige experten vonden dat dermatologen actiever cardiovasculaire risicofactoren zouden moeten behandelen, benadrukte ***Dr. Stockman*** vooral het belang van sensibilisering, screening en multidisciplinaire samenwerking met huisartsen, cardiologen, endocrinologen en andere specialisten. Volgens de panelleden evolueert de zorg voor psoriasis en alopecia areata steeds meer naar een geïntegreerd en multidisciplinair model waarbij niet alleen ziektecontrole, maar ook comorbiditeiten, levenskwaliteit en patiëntverwachtingen centraal staan.

Conclusies

Deze nieuwe editie van 'Aan tafel met PSO&AA' onderstreepte hoe zowel psoriasis als alopecia areata complexe inflammatoire aandoeningen zijn waarbij een gepersonaliseerde en multidisciplinaire aanpak essentieel is. Naast aandacht voor ziektecontrole kwamen ook comorbiditeiten, patiëntverwachtingen, therapierespons en kwaliteit van leven uitgebreid aan bod. De discussies benadrukten hierbij het belang van vroege en doelgerichte behandeling, realistische communicatie met patiënten en een nauwe samenwerking tussen verschillende disciplines.

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PHARMACEUTICAL FORM** Solution for injection The solution is clear and colourless to slightly yellow, with a pH not less than 5.2 and not more than 6.2, and an osmolality not less than 235 mOsm/kg and not more than 360 mOsm/kg. **4. CLINICAL PARTICULARS 4.1 Therapeutic indications** Plaque psoriasis Taltz is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Paediatric plaque psoriasis Taltz is indicated for the treatment of moderate to severe plaque psoriasis 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. 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 (see section 5.1). Axial spondyloarthritis 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 Creactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal antiinflammatory drugs (NSAIDs). Juvenile idiopathic arthritis (JIA) Juvenile psoriatic arthritis (JPsA) Taltz, alone or in combination with methotrexate, is indicated for the treatment of active JPsA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy. Enthesitis-related arthritis (ERA) Taltz, alone or in combination with methotrexate, is indicated for the treatment of active ERA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy. **4.2 Posology and method of administration** This medicinal product is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which it is indicated. Posology Plaque psoriasis in adults Pre-filled pen: The recommended dose is 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 (Q4W). Pre-filled syringe: Plaque psoriasis in adults The recommended dose is 160 mg by subcutaneous injection at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then maintenance dosing of 80 mg every 4 weeks (Q4W). Pre-filled pen and syringe: Paediatric plaque psoriasis (age 6 years and above) Efficacy and safety data is not available in children below the age of 6 years (see section 5.1). Available data do not support a posology below a body weight of 25 kg. The recommended dose given by subcutaneous injection in children is based on the following weight categories: **Children's body weight** Greater than 50 kg **Recommended starting dose (week 0)** 160 mg (two 80 mg injections) **Recommended dose every 4 weeks (Q4W) thereafter** 80 mg. **Children's body weight** 25 to 50 kg **Recommended starting dose (week 0)** 80 mg **Recommended dose every 4 weeks (Q4W) thereafter** 40 mg. In case no 40 mg presentation/syringe is available, ixekizumab doses of 40 mg and doses less than 80 mg must be prepared and administered by a qualified healthcare professional using the commercial Taltz 80 mg prefilled syringe. Use the Taltz 80 mg prefilled pen/syringe only in those children that require a dose of 80 mg and do not require dose preparation. Pre-filled pen and syringe Taltz is not recommended for use in children with a body weight below 25 kg. Paediatric body weights must be recorded and regularly rechecked prior to dosing. Psoriatic arthritis Pre-filled pen: The recommended dose is 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. Pre-filled syringe: The recommended dose is 160 mg by subcutaneous injection at week 0, followed by 80 mg 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) Pre-filled pen: The recommended dose is 160 mg (two 80 mg injections) by subcutaneous injection at week 0, followed by 80 mg every 4 weeks (see section 5.1 for further information). Pre-filled syringe: The recommended dose is 160 mg by subcutaneous injection at week 0, followed by 80 mg every 4 weeks (see section 5.1 for further information). Juvenile idiopathic arthritis (age 6 years and above) Juvenile psoriatic arthritis or enthesitis-related arthritis Efficacy and safety data is not available in children below the age of 6 years (see section 5.1). Available data do not support a posology below a body weight of 25 kg. The recommended dose given by subcutaneous injection in children is based on the following weight categories: **Children's body weight** Greater than 50 kg **Recommended starting dose (week 0)** 160 mg (two 80 mg injections) **Recommended dose every 4 weeks (Q4W) thereafter** 80 mg. **Children's body weight** 25 to 50 kg **Recommended starting dose (week 0)** 80 mg **Recommended dose every 4 weeks (Q4W) thereafter** 40 mg. Pre-filled pen: In case no 40 mg presentation is available, ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional using the commercial Taltz 80 mg prefilled syringe. Use the Taltz 80 mg prefilled pen only in those children that require a dose of 80 mg and do not require dose preparation. Pre-filled syringe: For children prescribed 80 mg, Taltz can be used directly from the pre-filled syringe. If the 40 mg pre-filled syringe is not available, doses less than 80 mg must be prepared by a healthcare professional. For instructions on preparation of Taltz 40 mg, see section 6.6. Pre-filled pen and syringe: 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. For all indications (plaque psoriasis in adults and children, psoriatic arthritis, axial spondyloarthritis, juvenile idiopathic arthritis including juvenile psoriatic arthritis and enthesitis-related arthritis) 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 is required in subjects aged ≥ 65 years (see section 5.2). There is limited information in subjects aged ≥ 75 years. Renal or hepatic impairment Taltz has not been studied in these patient populations. No dose recommendations can be made. Paediatric population Paediatric plaque psoriasis and juvenile idiopathic arthritis (juvenile psoriatic arthritis or enthesitis-related arthritis) (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 and juvenile idiopathic arthritis including juvenile psoriatic arthritis or enthesitis-related arthritis. Method of administration Pre-filled pen/syringe Subcutaneous use. Taltz is for subcutaneous injection. Injection sites may be alternated. If possible, areas of the skin that show psoriasis should be avoided as injection sites. The solution/the pen/the syringe must not be shaken. After proper training in subcutaneous injection technique, patients may self-inject Taltz if a healthcare professional determines that it is appropriate. However, the physician should ensure appropriate followup of patients. Comprehensive instructions for administration are given in the package leaflet and the user manual. Pre-filled syringe If the 40 mg pre-filled syringe is not available, doses less than 80 mg which require dose preparation should only be administered by a healthcare professional. For instructions on preparation of the medicinal product before administration, see section 6.6. **4.3 Contraindications** Serious hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Clinically important active infections (e.g. active tuberculosis, see section 4.4). **4.8 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). Tabulated list of adverse reactions Adverse reactions from clinical studies and post-marketing reports (Table 1) are listed by MedDRA system organ class. Within each system organ class, the adverse reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse reaction is based on the following convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000). A total of 8 956 patients have been treated with Taltz in blinded and openlabel clinical studies in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis, and other autoimmune conditions. Of these, 6 385 patients were exposed to Taltz for at least one year, cumulatively representing 19 833 adult patient years of exposure and 196 children cumulatively representing 343 patient years of exposure. **Table 1. List of adverse reactions in clinical studies and post-marketing reports Infections and infestations** Very common Upper respiratory tract infection Common Tinea infection, Herpes simplex (mucocutaneous) Uncommon Influenza, Rhinitis, Oral candidiasis, Conjunctivitis, Cellulitis Rare Oesophageal candidiasis **Blood and lymphatic system disorders** Uncommon Neutropenia, Thrombocytopenia **Immune system disorders** Uncommon Angioedema Rare Anaphylaxis **Respiratory, thoracic and mediastinal disorders** Common Oropharyngeal pain **Gastrointestinal disorders** Common Nausea Uncommon Inflammatory bowel disease **Skin and subcutaneous disorders** Uncommon Urticaria, Rash, Eczema Dyshidrotic eczema Rare Exfoliative dermatitis **General disorders and administration site conditions** Very common Injection site reactions[a] [a] See section description of selected adverse reactions Description of selected adverse reactions 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. In the adult plaque psoriasis studies, injection site reactions were more common in subjects with a body weight < 60 kg compared with the group with a body weight ≥ 60 kg (25 % vs. 14 % for the combined Q2W and Q4W groups). In the psoriatic arthritis studies, injection site reactions were more common in subjects with a body weight < 100 kg compared with the group with a body weight ≥ 100 kg (24 % vs. 13 % for the combined Q2W and Q4W groups). In the axial spondyloarthritis studies, injection site reactions were similar in subjects with a body weight < 100 kg compared with the group with a body weight ≥ 100 kg (14 % vs. 9 % for the combined Q2W and Q4W groups). The increased frequency of injection site reactions in the combined Q2W and Q4W groups did not result in an increase in discontinuations in either the plaque psoriasis, the psoriatic arthritis or the axial spondyloarthritis studies. The results described above are obtained with the original formulation of Taltz. In a single-blinded, randomised cross-over study in 45 healthy subjects comparing the original formulation with the revised, citrate-free formulation, statistically significantly lower Visual Analogue Scale (VAS) pain scores were obtained with the citrate-free vs. the original formulation during injection (difference in LS Mean VAS score -21.69) and 10 min after injection (difference in LS Mean VAS score -4.47). Infections In the placebocontrolled 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 (see section 4.4). Over the entire treatment period infections were reported in 52.8 % of patients treated with Taltz (46.9 per 100 patient years). Serious infections were reported in 1.6 % of patients treated with Taltz (1.5 per 100 patient years). 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. Laboratory assessment of neutropenia and thrombocytopenia In plaque psoriasis studies, 9% of patients receiving Taltz developed neutropenia. In most cases, the blood neutrophil count was ≥1 000 cells/mm^3. Such levels of neutropenia may persist, fluctuate or be transient. 0.1% of patients receiving Taltz developed a neutrophil count <1 000 cells/mm^3. In general, neutropenia did not require discontinuation of Taltz. 3% of patients exposed to Taltz had a shift from a normal baseline platelet value to <150 000 platelet cells/mm^3 to ≥75 000 cells/mm^3. Thrombocytopenia may persist, fluctuate or be transient. The frequency of neutropenia and thrombocytopenia in psoriatic arthritis and axial spondyloarthritis clinical studies is similar to that observed in the plaque psoriasis studies. Immunogenicity Approximately 9–17% of adult plaque psoriasis patients treated with Taltz at the recommended dosing regimen developed anti-drug antibodies, the majority of which were low titres and not associated with reduced clinical response up to 60 weeks of treatment. However, approximately 1% of patients treated with Taltz had confirmed neutralising antibodies associated with low drug concentrations and reduced clinical response. In psoriatic arthritis patients treated with Taltz at the recommended dosing regimen up to 52 weeks, approximately 11% developed anti-drug antibodies, the majority of which were low titre, and approximately 8% had confirmed neutralising antibodies. No apparent association between the presence of neutralising antibodies and impact on drug concentration or efficacy was observed. In paediatric psoriasis patients treated with Taltz at the recommended dosing regimen up to 12 weeks, 21 patients (18%) developed anti-drug antibodies, approximately half were low titer and 5 patients (4%) had confirmed neutralizing antibodies associated with low drug concentrations. There was no association with clinical response or adverse events. In radiographic axial spondyloarthritis patients treated with Taltz at the recommended dosing regimen up to 16 weeks, 5.2% developed antidrug antibodies, the majority of which were low titer, and 1.5% (3 patients) had neutralising antibodies (NAb). In these 3 patients, NAbpositive samples had low ixekizumab concentrations and none of these patients achieved an ASAS40 response. In nonradiographic axial spondyloarthritis patients treated with Taltz at the recommended dosing regimen for up to 52 weeks, 8.9% developed anti-drug antibodies, all of which were low titer; no patient had neutralising antibodies; and no apparent association between the presence of anti-drug antibodies and drug concentration, efficacy, or safety was observed. In juvenile idiopathic arthritis (juvenile psoriatic arthritis and enthesitis-related arthritis) patients treated with ixekizumab at the recommended dosing regimen up to 104 weeks, 18 patients (22.8 %) developed anti-drug antibodies, all of which were low to moderate titer. No apparent association between the presence of anti-drug antibodies and drug concentration, efficacy, or safety was observed. Across all indications, an association between immunogenicity and treatment emergent adverse events has not been clearly established. Paediatric population The safety profile observed in children with plaque psoriasis treated with Taltz every 4 weeks 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. In the paediatric clinical study, Crohn's disease occurred in 0.9% of patients in the Taltz group and 0% of patients in the placebo group during the 12week, placebocontrolled period. Crohn's disease occurred in a total of 4 Taltz treated subjects (2.0%) during the combined placebo-controlled and maintenance periods of the paediatric clinical study. Adverse drug reactions in paediatric patients treated with the recommended dose of ixekizumab by subcutaneous injection in the juvenile idiopathic arthritis (juvenile psoriatic arthritis or enthesitis-related arthritis) open-label clinical trial were consistent with the known safety profile of ixekizumab in the integrated safety dataset for paediatric plaque psoriasis indication as well as the adult indications of moderate to severe plaque psoriasis, psoriatic arthritis, and axial spondyloarthritis with the exception of frequencies for influenza (common), rhinitis (common) and conjunctivitis (common). Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: Belgium : Agence fédérale des médicaments et des produits de santé, www.afmps.be, Division Vigilance: Site internet: www.notifieruneffetindesirable.be, e-mail: adr@fagg-afmps.be. Luxembourg : Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé Site internet : www.guichet.lu/pharmacovigilance. **7. MARKETING AUTHORISATION HOLDER** Eli Lilly and Company (Ireland) Limited, Dunderrow, Kinsale, Co. Cork, Ireland. **8. MARKETING AUTHORISATION NUMBERS** Pre-filled pen: EU/1/15/1085/001 EU/1/15/1085/002 EU/1/15/1085/003 Pre-filled syringe: EU/1/15/1085/004 EU/1/15/1085/005 EU/1/15/1085/006 EU/1/15/1085/007 **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION** Date of first authorisation: 25 April 2016 Date of latest renewal: 17 December 2020 **10. DATE OF REVISION OF THE TEXT 26 March 2026 METHOD OF DELIVERY** Medicinal product subject to restricted medical prescription. Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu.

1. Taltz SPC, Eli Lilly, last approved version, www.afmps-fagg.be
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