אוגוסט 2018

רופא/ה נכבד/ה

רוקח/ת נכבד/ה

חברת לילי מבקשת להודיעכם כי העלונים של התכשיר Taltz 80 mg.

טקסט שהתווסף מודגש באדום, טקסט שהוסר מודגש ~~בכחול~~ והחמרות מודגשות בצהוב. קיימים עדכונים נוספים.

העלונים המעודכנים לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום :

אלי לילי ישראל בע"מ, השיזף 4, רעננה , טל': 09-9606234

בברכה,

ד"ר שרון אבנר
רוקחת ממונה

Taltz 80 mg solution for injection in a pre-filled pen
טאלץ 80 מ"ג, תמיסה להזרקה בעט מוכן לשימוש

Each pre-filled pen contains 80 mg ixekizumab in 1 ml.

העדכונים העיקריים בעלון לרופא הינם:

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.

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).

4.2 Posology and method of administration

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Taltz is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of ~~psoriasis~~ conditions for which Taltz is indicated.

Posology

Plaque psoriasis

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.

Psoriatic arthritis

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.

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.

Elderly (≥ 65 years)

No dose adjustment is required (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

The safety and efficacy of Taltz in children and adolescents aged 6 to 18 years in the treatment of moderate to severe plaque psoriasis have not yet been established. No data are available.

There is no relevant use of Taltz in children below the age of 6 years in the treatment of moderate to severe plaque psoriasis.

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.

4.4 Special warnings and precautions for use

Hypersensitivity

Serious hypersensitivity reactions, including some cases of anaphylaxis, angioedema, urticaria and, rarely, late (10-14 days following injection) serious hypersensitivity reactions including widespread

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urticaria, dyspnea and high antibody titres have been reported. If a serious hypersensitivity reaction occurs, administration of Taltz should be discontinued immediately and appropriate therapy initiated.

4.5 Interaction with other medicinal products and other forms of interaction

In plaque psoriasis studies, the safety of Taltz in combination with other immunomodulatory agents or phototherapy has not been evaluated.

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No interaction was seen when Taltz was administered concomitantly with methotrexate (MTX) and/or corticosteroids in patients with psoriatic arthritis.

4.8 Undesirable effects

Tabulated list of adverse reactions

ADRs from clinical studies and postmarketing reports (Table 1) are listed by MedDRA system organ class. Within each system organ class, the ADRs are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each ADR 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 ~~4204~~ 7,339 patients ~~were~~ have been treated with Taltz in blinded and open-label clinical ~~development~~ studies in plaque psoriasis, psoriatic arthritis, and other autoimmune conditions. Of these, ~~2190 psoriasis~~ 4,500 patients were exposed to Taltz for at least one year, cumulatively representing ~~3531~~ 13,645.6 patient years of exposure.

In plaque psoriasis, three placebo-controlled phase III studies ~~in plaque psoriasis~~ were integrated to evaluate the safety of Taltz in comparison to placebo up to 12 weeks after treatment initiation. A total of 3,119 patients were evaluated (1,161 patients on 80 mg every 4 weeks (Q4W), 1,167 patients on 80 mg every 2 weeks (Q2W) and 791 patients on placebo).

In psoriatic arthritis, two placebo-controlled phase III studies were integrated to evaluate the safety of Taltz in comparison to placebo up to 24 weeks after treatment initiation. A total of 678 patients were evaluated (229 patients on 80 mg every 4 weeks (Q4W), 225 patients on 80 mg every 2 weeks (Q2W) and 224 patients on placebo). The safety profile observed in patients with psoriatic arthritis treated with Taltz is consistent with the safety profile in plaque psoriasis with the exception of the frequencies of the adverse reactions of influenza and conjunctivitis which were common in patients with psoriatic arthritis.

Table 1. List of adverse reactions in clinical studies[a] and postmarketing reports

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System Organ Class	Frequency	Adverse reaction
Infections and infestations	Very Common	Upper respiratory tract infection[b]
	Common	Tinea infection, Herpes simplex (mucocutaneous)[c]
	Uncommon	Influenza[i], Rhinitis, Oral candidiasis[d], Conjunctivitis[i], Cellulitis[e]
Blood and lymphatic system disorders	Uncommon	Neutropenia[g], Thrombocytopenia[g]
Immune system disorders	Uncommon	Angioedema
	Rare	Anaphylaxis[h]
Respiratory, thoracic and mediastinal disorders	Common	Oropharyngeal pain
Gastrointestinal disorders	Common	Nausea
Skin and subcutaneous disorders	Uncommon	Urticaria, Rash, Eczema
General disorders and administration site conditions	Very common	Injection site reactions[f]

[a] *Placebo-controlled clinical studies (phase III) in moderate to severe plaque psoriasis patients exposed to ixekizumab 80 mg Q2W, ixekizumab 80 mg Q4W or placebo for up to 12 weeks of treatment duration, or in active psoriatic arthritis patients exposed to ixekizumab 80 mg Q2W, ixekizumab 80 mg Q4W or placebo for up to 24 weeks of treatment duration.*

[b] *Upper respiratory tract infection includes nasopharyngitis and upper respiratory tract infection*

[c] *Herpes simplex (mucocutaneous) is defined as events with the preferred terms Oral herpes, Herpes simplex, Genital herpes, Herpes dermatitis, and Genital herpes simplex*

[d] *Oral candidiasis defined as events with the preferred terms oral candidiasis and oral fungal infection*

[e] *Cellulitis includes staphylococcal and external ear cellulitis, and erysipelas*

[f] *In the 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). 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 or the psoriatic arthritis studies*

[g] *Based on reported adverse events*

[h] *Based on postmarketing reports*

[i] *Adverse drug reactions in patients treated with ixekizumab in the plaque psoriasis and psoriatic arthritis clinical trials were similar with the exception of the frequencies of influenza (common) and conjunctivitis (common) in the psoriatic arthritis clinical trials*

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Description of selected adverse reactions

(Based on adverse reactions data from 4,204 patients with moderate to severe plaque psoriasis [4,729.7 patient years] and 1,117 patients with active psoriatic arthritis [1,050.6 patient years] who have received at least 1 dose of ixekizumab.)

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Infection rates observed in psoriatic arthritis 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 <1000 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 clinical studies is similar to that observed in the plaque psoriasis studies.

Immunogenicity

Approximately 9–17 % of 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.

An association between immunogenicity and treatment emergent adverse events has not been clearly established.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Taltz has been shown to lower (within 1 week of treatment) levels of C-reactive protein, which is a marker of inflammation.

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Psoriatic arthritis

The safety and efficacy of Taltz were assessed in two randomised, double-blind, placebo-controlled phase III studies in 780 patients with active psoriatic arthritis (≥3 swollen and ≥3 tender joints). Patients in these studies had a diagnosis of psoriatic arthritis (Classification Criteria for Psoriatic Arthritis [CASPAR]

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criteria) for a median of 5.33 years. Randomised patients also had current plaque psoriasis skin lesions (94.0%) or a documented history of plaque psoriasis, with 12.1% of patients with moderate to severe plaque psoriasis at baseline. Over 58.9% and 22.3% of the psoriatic arthritis patients had enthesitis and dactylitis at baseline, respectively. For both studies, the primary endpoint was American College of Rheumatology (ACR) 20 response at Week 24.

In Psoriatic Arthritis Study 1 (SPIRIT-P1), patients naive to biologic therapy with active psoriatic arthritis were randomised to subcutaneous injections of placebo, adalimumab 40 mg once every 2 weeks (active control reference arm), Taltz 80 mg once every 2 weeks (Q2W), or 80 mg once every 4 weeks (Q4W). Both Taltz regimens included a 160 mg starting dose. 85.3% of patients in this study had received prior treatment with ≥1 cDMARD. 53% of patients had concomitant use of MTX at a mean weekly dose of 15.8 mg. 67% of patients who had concomitant use of MTX had a dose of 15 mg or greater. Patients in all treatment groups with an inadequate response at week 16 received rescue therapy (modification to background therapy). Patients on Taltz Q2W or Q4W remained on their originally assigned dose of Taltz. Patients receiving adalimumab or placebo were re-randomised 1:1 to Taltz Q2W or Q4W at week 16 or 24 based on responder status.

Psoriatic Arthritis Study 2 (SPIRIT-P2) enrolled patients who were previously treated with an anti-TNF agent and discontinued the anti-TNF agent for either lack of efficacy or intolerance (anti-TNF-IR patients). Patients were randomised to subcutaneous injections of placebo, Taltz 80 mg once every 2 weeks (Q2W), or 80 mg once every 4 weeks (Q4W). Both Taltz regimens included a 160 mg starting dose. 56% and 35% of patients were inadequate responders to 1 anti-TNF or 2 anti-TNF, respectively. SPIRIT-P2 evaluated 363 patients, of whom 41% had concomitant use of MTX at a mean weekly dose of 16.1 mg. 73.2% of patients who had concomitant use of MTX had a dose of 15 mg or greater. Patients in all treatment groups with an inadequate response at week 16 received rescue therapy (modification to background therapy). Patients in Taltz Q2W or Q4W remained on their originally assigned dose of Taltz. Patients receiving placebo were re-randomised 1:1 to Taltz Q2W or Q4W at week 16 or 24 based on responder status.

Signs and symptoms

Treatment with Taltz resulted in significant improvement in measures of disease activity compared to placebo at Week 24 (see Table 6).

Table 6. Efficacy results in SPIRIT-P1 and SPIRIT-P2 at week 24

	SPIRIT-P1						SPIRIT-P2				
Endpoints					Difference from Placebo in Response Rate (95% CI)					Difference from Placebo in Response Rate (95% CI)	
	PBO (N = 106)	Taltz Q4W (N = 107)	Taltz Q2W (N = 103)	ADA (N = 101)	Taltz Q4W	Taltz Q2W	PBO (N = 118)	Taltz Q4W (N = 122)	Taltz Q2W (N = 123)	Taltz Q4W	Taltz Q2W
ACR 20 response, n (%)											
Week 24	32 (30.2)	62 (57.9)	64 (62.1)	58 (57.4)	27.8 (15.0, 40.6)[c]	31.9 (19.1, 44.8)[c]	23 (19.5)	65 (53.3)	59 (48.0)	33.8 (22.4, 45.2)[c]	28.5 (17.1, 39.8)[c]

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Endpoints	SPIRIT-P1						SPIRIT-P2				
					Difference from Placebo in Response Rate (95% CI)					Difference from Placebo in Response Rate (95% CI)	
	PBO (N = 106)	Taltz Q4W (N = 107)	Taltz Q2W (N = 103)	ADA (N = 101)	Taltz Q4W	Taltz Q2W	PBO (N = 118)	Taltz Q4W (N = 122)	Taltz Q2W (N = 123)	Taltz Q4W	Taltz Q2W
ACR 50 response, n (%)											
Week 24	16 (15.1)	43 (40.2)	48 (46.6)	39 (38.6)	25.1 (13.6, 36.6)[c]	31.5 (19.7, 43.3)[c]	6 (5.1)	43 (35.2)	41 (33.3)	30.2 (20.8, 39.5)[c]	28.3 (19.0, 37.5)[c]
ACR 70 response, n (%)											
Week 24	6 (5.7)	25 (23.4)	35 (34.0)	26 (25.7)	17.7 (8.6, 26.8)[c]	28.3 (18.2, 38.5)[c]	0	27 (22.1)	15 (12.2)	22.1 (14.8, 29.5)[c]	12.2 (6.4, 18.0)[c]
Minimal Disease Activity n (%)											
Week 24	16 (15.1)	32 (29.9)	42 (40.8)	32 (31.7)	14.8 (3.8, 25.8)[a]	25.7 (14.0, 37.4)[c]	4 (3.4)	34 (27.9)	29 (23.6)	24.5 (15.9, 33.1)[c]	20.2 (12.0, 28.4)[c]
ACR 50 and PASI 100 in patients with ≥3% BSA psoriasis skin involvement at baseline, n (%)											
Week 24	1 (1.5)	21 (28.8)	19 (32.2)	9 (13.2)	27.3 (16.5, 38.1)[c]	30.7 (18.4, 43.0)[b]	0 (0.0)	12 (17.6)	10 (14.7)	17.6 (8.6, 26.7)[c]	14.7 (6.3, 23.1)[c]

Abbreviations: ACR 20/50/70 = American College of Rheumatology 20%/50%/70% response rate; ADA = adalimumab; BSA = body surface area; CI = confidence interval; Q4W = Taltz 80 mg every 4 weeks; Q2W = Taltz 80 mg every 2 weeks; N = number of patients in the analysis population; n = number of patients in the specified category; NRI = non-responder imputation; PASI 100 = psoriasis area and severity index 100% improvement; PBO = placebo.

Note: patients who were rescued at week 16 or discontinued or with missing data were imputed as non-responders for week 24 analyses.

Concomitant cDMARDs included MTX, leflunomide and sulfasalazine.

[a] $p<0.05$; [b] $p<0.01$; [c] $p<0.001$ compared with placebo.

In patients with pre-existing dactylitis or enthesitis, treatment with Taltz Q4W resulted in improvement in dactylitis and enthesitis at Week 24 compared to placebo (resolution: 78% vs. 24%; p<0.001, and 39% vs. 21%; p<0.01, respectively).

In patients with ≥3% BSA, the improvement in skin clearance at Week 12 as measured by 75% improvement in Psoriasis Area Severity Index (PASI 75), was 67% (94/141) for those treated with the Q4W dosing regimen, and 9% (12/134) for those treated with placebo (p<0.001). The proportion of patients achieving a PASI 75, PASI 90, and PASI 100 response at Week 24 was greater with Taltz Q4W compared to placebo (p<0.001). In patients with concomitant moderate to severe psoriasis and psoriatic arthritis, Taltz Q2W dose regimen showed significantly higher response rate for PASI75, PASI 90 and PASI

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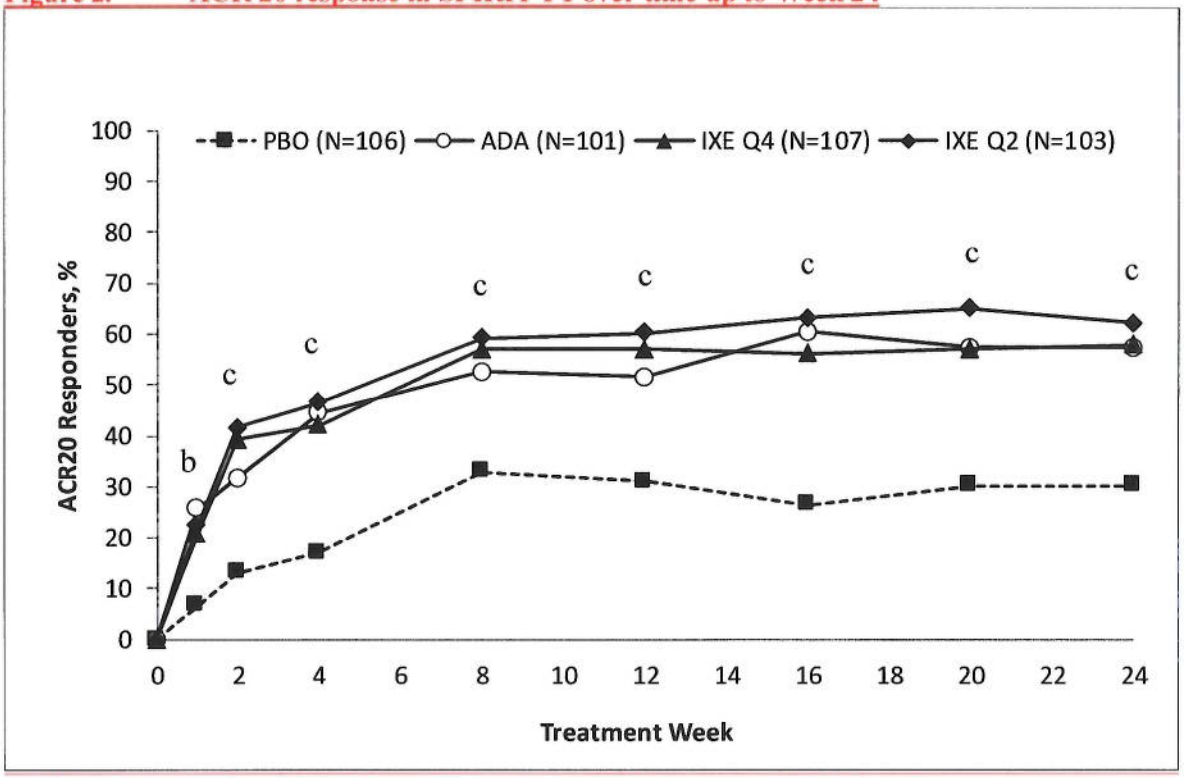
100 compared to placebo (p<0.001) and demonstrated clinically meaningful benefit over the Q4W dose regimen.

The treatment responses on Taltz were significantly greater than those on placebo as early as week 1 for ACR 20, week 4 for ACR 50 and week 8 for ACR 70 and persisted through week 24.

Figure 2. ACR 20 response in SPIRIT-P1 over time up to Week 24



For both Taltz Q2W and Q4W: [b] p<0.01 and [c] p<0.001 compared with placebo.

In SPIRIT-P1 and SPIRIT-P2, similar responses for ACR 20/50/70 were seen in patients with psoriatic arthritis regardless of whether they were on concomitant cDMARDs, including MTX treatment, or not.

In SPIRIT-P1 and SPIRIT-P2, improvements were shown in all components of the ACR scores including patient assessment of pain. At Week 24 the proportion of patients achieving a modified Psoriatic Arthritis Response Criteria (PsARC) response was greater in the Taltz-treated patients compared to placebo.

In SPIRIT-P1, efficacy was maintained up to Week 52 as assessed by ACR 20/50/70, MDA, enthesitis resolution, dactylitis resolution, and PASI 75/90/100 response rates.

The efficacy and safety of Taltz was demonstrated regardless of age, gender, race, disease duration, baseline body weight, baseline psoriasis involvement, baseline CRP, baseline DAS28-CRP, concomitant corticosteroid use, and previous treatment with a biologic. Taltz was efficacious in biologic-naive, biologic-exposed and biologic-failure patients.

Radiographic response

In SPIRIT-P1, inhibition of progression of structural damage was assessed radiographically and expressed as the change in modified total Sharp Score (mTSS) and its components, the Erosion Score

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(ES) and the Joint Space Narrowing score (JSN) at Weeks 24 and 52, compared to baseline. Week 24 data are presented in Table 7.

Table 7. Change in modified Total Sharp Score in SPIRIT-P1

					Difference from Placebo (95% CI)	
	PBO (N = 106)	Taltz Q4W (N = 107)	Taltz Q2W (N = 103)	ADA (N = 101)	Taltz Q4W	Taltz Q2W
Baseline score, mean (SD)	17.6 (28.62)	19.2 (32.68)	15.2 (28.86)	15.9 (27.37)	NA	NA
Change from baseline at Week 24, LSM (SE)	0.51 (0.092)	0.18 (0.090)	0.09 (0.091)	0.13 (0.093)	-0.33 (-0.57,-0.09)[b]	-0.42 (-0.66,-0.19)[c]

Abbreviations: ADA = adalimumab; CI = confidence interval; Q4W = Taltz 80 mg every 4 weeks; Q2W = Taltz 80 mg every 2 weeks; LSM = least squares mean; N = number of patients in the analysis population; PBO = placebo; SE = standard error.

[b] p<0.01; [c] p<0.001 compared with placebo.

Radiographic joint damage progression was inhibited by Taltz (Table 7) at Week 24, and the percentage of patients with no radiographic joint damage progression (defined as a change from baseline in mTSS of ≤0.5) from randomisation to Week 24 was 94.8% for Taltz Q2W (p<0.001), 89.0% for Taltz Q4W (p=0.026), 95.8% for adalimumab (p<0.001), all compared to 77.4% for placebo. At Week 52, the mean change from baseline in mTSS was 0.27 for placebo/Taltz Q4W, 0.54 for Taltz Q4W/Taltz Q4W, and 0.32 for adalimumab/Taltz Q4W. The percentage of patients with no radiographic joint damage progression from randomisation to Week 52 was 90.9% for placebo/Taltz Q4W, 85.6% for Taltz Q4W/Taltz Q4W, and 89.4% for adalimumab/Taltz Q4W.

Physical function and health-related quality of life

In both SPIRIT-P1 and SPIRIT-P2, patients treated with Taltz Q2W (p<.001) and Q4W (p<.001) showed significant improvement in physical function compared to patients treated with placebo as assessed by Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 24, and maintained at Week 52 in SPIRIT-P1.

Taltz-treated patients reported improvements in health-related quality of life as measured by the Physical Component Summary of the Short Form-36 Health Survey (SF-36 PCS) score (p<.001). There were also improvements demonstrated in fatigue as assessed by Fatigue severity NRS scores (p<0.001).

5.2 Pharmacokinetic properties

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Psoriatic arthritis

The pharmacokinetic properties of Taltz observed in psoriatic arthritis patients were similar to those displayed in plaque psoriasis patients. The bioavailability of Taltz in psoriatic arthritis patients was in the range of 61-84% on the basis of the population pharmacokinetic model.

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Elderly

Of the 4,204 plaque psoriasis patients exposed to Taltz in clinical studies, a total of 301 were 65 years of age or older and 36 patients were 75 years of age or older. Of the 1,118 psoriatic arthritis patients exposed to Taltz in clinical studies, a total of 122 patients were 65 years of age or older and 6 patients were 75 years of age or older.

Based on population pharmacokinetic analysis with a limited number of elderly patients (n = 94 for age ≥ 65 years and n = 12 for age ≥ 75 years), clearance in elderly patients and patients less than 65 years of age was similar.

העדכונים העיקריים בעלון לצרכן הינם:

1. למה מיועדת התרופה?

ספחת רובדית

טאלץ מיועדת לטיפול בספחת רובדית (פלאק פסוריאזיס) בינונית עד חמורה במבוגרים אשר מתאימים לטיפול סיסטמי (מערכתי).

דלקת מפרקים פסוריאטית

טאלץ מיועדת לטיפול במצב שנקרא "דלקת מפרקים פסוריאטית", מחלה דלקתית של המפרקים, המלווה לעיתים קרובות בפסוריאזיס (ספחת). אם יש לך דלקת מפרקים פסוריאטית, תקבל תחילה תרופות אחרות. אם אתה לא מגיב מספיק טוב לתרופות אלה, תקבל **טאלץ** כדי להפחית את הסימפטומים של המחלה. ניתן להשתמש ב**טאלץ** לבדו או עם תרופה אחרת בשם מתוטרקסאט.

השימוש ב**טאלץ** יסייע לך על-ידי הפחתת הסימפטומים של המחלה, שיפור התפקוד הפיזי (היכולת לעשות פעילות יומיומית רגילה), וכן להאט את הנזק למפרקים.

קבוצה תרפויטית:

איקסקיזומאב שייך לקבוצת תרופות שנקראות מעכבי אינטרלויקין (interleukin (IL) inhibitors). תרופה זאת פועלת על-ידי ניטרול הפעילות של חלבון שנקרא IL-17A, שמעורב בהתפתחות ספחת ודלקת מפרקים פסוריאטית.

2. לפני השימוש בתרופה

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אזהרות מיוחדות הנוגעות לשימוש בתרופה

לפני השימוש ב**טאלץ** ספר לרופא, אם:

Eli Lilly Israel Ltd. 4 HaSheizaf St.
P.O.Box 4246 Ra'anana 4366411
Tel: 09-9606234, Fax: 09-9576001

אלי לילי ישראל בע"מ, השיזף 4
ת.ד. 4246 רעננה 4366411
טלפון: 09-9606234, פקס: 09-9576001

- הנך סובל מזיהום או הנך-סובל מזיהומים ממושכים או חוזרים.
- הנך חולה במחלת קרוהן.
- יש לך דלקת כיבית של המעי הגס (ulcerative colitis).
- הנך מקבל טיפול אחר כלשהו נגד ספחת (כגון טיפול שמדכא את מערכת החיסון או טיפול באור אולטרה-סגול) או נגד דלקת מפרקים פסוריאטית.

3. כיצד תשתמש בתרופה?

מינון ומשך השימוש

דלקת מפרקים פסוריאטית

עבור חולי דלקת מפרקים פסוריאטית הסובלים גם מספחת רובדית בינונית עד חמורה:

- המנה הראשונה היא 160 מ"ג (שתי הזרקות של 80 מ"ג) בהזרקה תת-עורית. את המנה הזאת יכולים לתת לך הרופא שלך או אחות.
- לאחר המנה הראשונה, תשתמש במנה של 80 מ"ג (הזרקה אחת) בשבועות 2, 4, 6, 8, 10 ו-12. החל משבוע 12, תשתמש במנה של 80 מ"ג (הזרקה אחת) כל ארבעה שבועות.

עבור חולי דלקת מפרקים פסוריאטית אחרים:

- המנה הראשונה היא 160 מ"ג (שתי הזרקות של 80 מ"ג) בהזרקה תת-עורית. את המנה הזאת יכולים לתת לך הרופא שלך או אחות.
- לאחר המנה הראשונה, תשתמש במנה של 80 מ"ג (הזרקה אחת) כל ארבעה שבועות.

אם אתה מפסיק להשתמש בטאלץ

אל תפסיק להשתמש בטאלץ בלי לדבר תחילה עם הרופא שלך. אם תפסיק את הטיפול, התסמינים של ספחת או דלקת מפרקים פסוריאטית עלולים לחזור.

4. תופעות לוואי

תגובה אלרגית חמורה (~~שכיחות אינה ידועה – לא ניתן להעריך את השכיחות על סמך הנתונים הקיימים~~ מופיע בעד משתמש אחד מבין 1,000 משתמשים) – הסימנים יכולים לכלול:

...

- לחץ דם נמוך, אשר יכול לגרום לסחרחורת

תופעות לוואי נוספות

תופעות לוואי שכיחות (common) - תופעות שמופיעות בעד משתמש אחד מתוך 10:

...

- פצעים בחלל הפה (אפתה), העור והקרום הרירי (הרפס סימפלקס)

תופעות לוואי שאינן שכיחות (uncommon) - תופעות שמופיעות בעד משתמש אחד מתוך 100:

...

אקזמה

פריחה

התנפחות מהירה של רקמות הצוואר, הפנים, הפה או הגרון (אנגיואדמה)

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העדכונים העיקריים בעלון למשתמש הינם:

1 הכנה

1א הוצא את העט המוכן לשימוש מן המקרר. השאר את מכסה הבסיס על העט עד שתהיה מוכן להזריק. **המתן 30 דקות** על מנת לאפשר לעט המוכן לשימוש להתחמם לטמפרטורת החדר לפני שאתה משתמש בו.

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