אוגוסט 2021

רופא/ה נכבד/ה

רוקח/ת נכבד/ה

חברת לילי מבקשת להודיעכם כי העלון לרופא של התכשיר Taltz 80 mg עודכן. מידע שהתווסף מסומן בכחול.

העלון לרופא המעודכן המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבל מודפס על ידי פנייה לבעל הרישום: אלי לילי ישראל בע"מ, השיזף 4, רעננה טל': 09-9606234

בברכה,
רונן שוורץ
רוקח ממונה

Taltz 80 mg

טאלץ 80 מ"ג \ 1 מ"ל

מרכיב פעיל: IXEKIZUMAB 80 mg/ml

ההתוויה המאושרת לתכשיר:

Plaque psoriasis:

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

Psoriatic arthritis:

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

Ankylosing spondylitis (radiographic axial sponyloarthritis)

Taltz is indicated for the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Non -radiographic axial spondyloarthritis

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

העדכון בעלון לרופא הינו:

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5.1 Pharmacodynamic properties

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Health-related outcomes

Spinal pain showed improvements versus placebo as early as week 1 and was maintained through week 16 [Taltz vs placebo: COAST-X: -2.4 vs -1.5]. In addition, more patients on Taltz compared with placebo achieved good health status (ASAS HI ≤5) at week 16 and week 52.

Long-term outcomes Axial Spondyloarthritis

Patients who completed one of the three pivotal studies COAST-V/W/X (52 weeks) were offered participation in a long-term extension and randomised withdrawal study (COAST-Y, with 350 and 423 patients enrolled on Taltz Q4W and Q2W, respectively). Among those who achieved remission 157/773 (20.3%) (Ankylosing Spondylitis Disease Activity Score [ASDAS] <1.3 at least once, and no ASDAS score ≥2.1, at weeks 16 and 20), 155 patients exposed to Taltz up to 76 weeks were randomised at week 24 of the COAST-Y study (Placebo, N=53; Taltz Q4W, N=48; and Taltz Q2W, N=54); of these, 148 (95.5%) completed the week 64 visit (Placebo, N=50; Taltz Q4W, N=47; Taltz Q2W, N=51). The primary endpoint was the proportion of patients in the randomised withdrawal population who did not experience a flare during weeks 24-64 (combined Taltz Q2W and Taltz Q4W groups versus placebo). A significantly larger proportion of patients (NRI) in the combined Taltz groups (83.3% (85/102), p<0.001) and Taltz Q4W (83.3 % (40/48), p=0.003) had no flare during weeks 24-64 compared with those who withdrew from Taltz to placebo (54.7 % (29/53)). Taltz (in both combined Taltz groups and Taltz Q4W group) significantly delayed the time to flare (Log-Rank Test p<0.001 and p<0.01, respectively) compared to Placebo.

In patients who received Taltz Q4W continuously (N=157), the ASAS40, ASDAS <2.1 and BASDAI50 responses were maintained to Week 116.

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