J-C Health Care Ltd.

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ינואר 2022

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא בתכשיר:

TREMFYA (Guselkumab 100 mg)

התוויה:

Plaque psoriasis
Tremfya is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Psoriatic arthritis
Tremfya, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

4.4 Special warnings and precautions for use

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
…

4.8 Undesirable effects

…
Transaminase increases from > 3 to ≤ 5 x ULN and > 5 x ULN were low in frequency, occurring more often in the Tremfya q4w group compared with the Tremfya q8w group (Table 2).
~~Through 1 year, in most cases, the increase in transaminases was transient and did not lead to discontinuation of treatment.~~
…
In the psoriasis clinical studies, through 1 year, the frequency of transaminase increases (ALT and AST) for the Tremfya q8w dose was similar to that observed for the Tremfya q8w dose in the psoriatic arthritis clinical studies. Through 5 years, the incidence of transaminase elevation did not increase by year of guselkumab treatment. Most transaminase increases were ≤ 3 x ULN.

In most cases, the increase in transaminases was transient and did not lead to discontinuation of treatment
…
Gastroenteritis
… Through Week 264, 5.8% ~~156, 4.9%~~ of all Tremfya-treated patients reported gastroenteritis. Adverse reactions of gastroenteritis were non-serious and did not lead to discontinuation of Tremfya through Week 264 ~~156~~.
…
Injection site reactions
... Through Week 264 ~~156~~, 0.4% ~~0.5%~~ of Tremfya injections were associated with injection site reactions. Injection site ~~Advrse~~ reactions ~~of injection site erythema and injection site pain were the most commonly reported events of injection site reaction and~~ were generally mild to moderate in severity, none were serious, and ~~none~~ one led to discontinuation of Tremfya.

Immunogenicity
... In pooled phase III analyses in patients with psoriasis, approximately ~~9%~~ 15% of patients treated with

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Tremfya developed antidrug antibodies in up to ~~156~~264 weeks of treatment. Of the patients who developed antidrug antibodies, approximately 5% had antibodies that were classified as neutralizing, which equates to 0.76% of all patients treated with Tremfya. Antidrug antibodies were not associated with lower efficacy or development of injection-site reactions.

5.1 Pharmacodynamic properties

…

Table 6: Summary of Patient Reported Outcomes in the Open-Label Phase in VOYAGE 1

	Guselkumab			Adalimumab-Guselkumab		
	Week 76	Week 156	Week 252	Week 76	Week 156	Week 252
DLQI score > 1 at baseline, n	445	~~411~~ 420	374	264	~~251~~ 255	235
Subjects with DLQI 0/1	337 (75.7%)	~~307 (74.7%)~~ 308 (73.3%)	272 (72.7%)	198 (75.0%)	190 (74.5%) ~~(75.7%)~~	174 (74.0%)
PSSD Symptom Score, subjects with baseline score > 0	347	~~319~~ 327	297	227	~~214~~ 218	200
Symptom score = 0, n (%)	136 (39.2%)	~~129 (40.4%)~~ 130 (39.8%)	126 (42.4%)	99 (43.6%)	96 (44.~~9~~0%)	96 (48.0%)
PSSD Sign score, subjects with baseline score > 0	347	~~319~~ 327	297	228	~~215~~ 219	201
Sign score = 0, n (%)	102 (29.4%)	~~93 (29.2%)~~ 94 (28.7%)	98 (33.0%)	71 (31.1%)	69 (31.5%) ~~(32.1%)~~	76 (37.8%)

כלל השינויים מסומנים בעלון המצורף כאשר הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוק הוסר.
העלון לרופא נשלח לפרסום במלואו למאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבלו מודפס בפניה אלינו לטלפון 09-9591111 .

להלן העדכונים.

בברכה,
אלינה ורמן
רוקחת ממונה