

מרץ 2020

Xamiol, gel

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר **קסמיאול**.

בהודעה זו מפורטים העדכונים המהותיים שבוצעו. למידע מלא יש לעיין בעלון.

בנוסף, עבור **אריזת הבקבוק** אושר עדכון ח"י המדף ל-3 שנים וח"י המדף לאחר פתיחה ראשונה: ניתן להשתמש במשך 6 חודשים.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Betamethasone (as dipropionate) 0.5 mg / 1 g
Calcipotriol (as hydrate) 50 mcg / 1 g

התוויה מאושרת:

Topical treatment of psoriasis vulgaris on the scalp and topical treatment of mild to moderate "non-scalp" plaque psoriasis vulgaris in adults 18 years of age and older.

העלון לרופא עודכן במרץ 2020. להלן העדכונים (מסומנים באדום):

4.8 Undesirable effects

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Paediatric population

No clinically relevant differences between the safety profiles in adult and adolescent populations have been observed.

A total of 216 adolescent subjects were treated in three open label clinical trials.

See section 5.1 for further details regarding the trials.

~~No new adverse events and no new adverse reactions were seen in 109 adolescents aged 12-17 years with scalp psoriasis treated with Xamiol gel for 8 weeks. However, due to the size of the studies, no firm conclusion can be drawn as to the safety profile of Xamiol gel in adolescents compared to that in adults. See section 5.1.~~

5.1 Pharmacodynamic properties

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Paediatric population

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Scalp and body

Effects on calcium metabolism were investigated in one uncontrolled open 8-week trial in 107 adolescents aged 12-17 years with scalp and body psoriasis who used up to 114.2 g per week of Xamiol gel. No cases of hypercalcaemia and no clinically relevant changes in urinary calcium were reported. The adrenal response to ACTH challenge was measured in 31 patients; five patients showed a decrease in cortisol response to ACTH challenge where 2 of the 5 patients showed only borderline decreases. Four of the patients showed decrease after 4 weeks of treatment and 2 showed decrease after 8 weeks including 1 patient showing a decrease at both periods. These events were mild, without clinical manifestations, and reversible.