



יוני 2022

רופא /ה, רוקח/ת נכבד/ה,
חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

Optalgin Teva Solution for I.V. or I.M. Injection

אופטלגין טבע

תמיסה להזרקה לתוך הוריד או לתוך השריר

כל אמפולה של 2 מ"ל מכילה: *Dipyrone 1g*

עדכון בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

As an analgesic:

Optalgin Teva solution for injection, by intravenous administration, is indicated for the relief of severe and acute pain when oral treatment is not feasible or suitable, as in post-traumatic or post-surgical pain, biliary or renal colic, and pain associated with malignant diseases.

As an antipyretic:

Optalgin Teva solution for injection, by intramuscular administration, is indicated to lower temperature in life-threatening situations, when this cannot be achieved by other means.

Hyperthermic patients in critical condition may also be treated in non-hospital environment, under close medical supervision.

ברצוננו להודיע שהעלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והחמרות על רקע צהוב. הסרות מידע מסומנות בקו-חוצה):

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4.4 Special warnings and precautions for use

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Severe skin reactions

~~The life-threatening skin~~ Severe cutaneous adverse reactions (SCARs), including reactions Stevens-Johnson syndrome (SJS), ~~and~~ toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening, or fatal, have been reported in connection with ~~during use of~~ dipyrone therapy.

The patients are to be informed about the signs and symptoms and monitored closely for skin reactions.



If signs or symptoms **suggestive of these reactions occur**, of SJS or TEN develop (such as progressive skin eruption. Often with blisters or mucosal lesions), treatment with Optalgin® Teva 1 g/2 ml solution for injection **should be discontinued** must be stopped immediately and dipyrone must not be resumed at any stage (see section 4.3). ~~should never be introduced.~~

~~Patients should be alerted to the signs and symptoms and closely monitored for skin reactions, especially in the first weeks of treatment.~~

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4.8 Undesirable effects

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Skin and subcutaneous tissue disorders

Uncommon:

Fixed drug eruption.

Rare:

Rash (e.g. maculopapular rash).

Very rare:

Stevens-Johnson syndrome or toxic epidermal necrolysis (see section 4.4).

Not known:

Drug reaction with eosinophilia and systemic symptoms (DRESS, see section 4.4).

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העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
וניתן לקבלו מודפס ע"י פניה לחברת טבע. <https://israeldrugs.health.gov.il>