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

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

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 והסרות מידע ~~כשקסט מחוק~~):

…..

4.4 Special warnings and precautions for use

Optalgin® Teva 1 g/2 ml solution for injection contains the pyrazolone derivative metamizole and carries the rare but life-threatening risks of shock and agranulocytosis (see section 4.8).

טבע תעשיות פרמצבטיות בע"מ
רח' התאנה 1, פארק תעשיה חמ"ן ת.ד. 975, שוהם 6085001 |
www.tevapharm.com

Patients who display anaphylactoid reactions to dipyrone are at particular risk of reacting in the same way to other non-narcotic analgesics.

Patients who display an anaphylactic or other immunologically mediated reaction (e.g. agranulocytosis) to dipyrone are also at particular risk of reacting in the same way to other pyrazolones and pyrazolidines.

Patients who display an anaphylactic or other immunologically mediated reaction to other pyrazolones, pyrazolidines or other non-narcotic analgesics are also at high risk of having such a reaction to Optalgin Teva 1 g/2 ml solution for injection.

Agranulocytosis

~~If signs of agranulocytosis or thrombocytopenia appear (see section 4.8), the administration of Optalgin® Teva 1 g/2 ml solution for injection must be stopped immediately and a blood count (including differential blood count) must be performed. The treatment must be stopped without waiting for the results of the laboratory tests.~~

The treatment must be suspended immediately as soon as neutropenia (<1,500 neutrophils/mm^3) occurs and the full blood count monitored until it returns to normal.

If the following signs and symptoms occur, patients should be instructed to stop using this medicinal product immediately and seek medical advice: unexpected deterioration in their general condition (such as fever, rigor, sore throat, difficulty swallowing), refractory or new-onset fever and painful mucosal changes, especially in the region of the mouth, nose and throat or in the genital or anal region. The use of Optalgin Teva 1g/2ml solution for injection must be stopped immediately and the blood count (including differential blood count) checked. Do not wait for the results of the laboratory tests before stopping the treatment (see section 4.8).

Thrombocytopenia

If signs of thrombocytopenia occur such as an increased bleeding tendency and petechiae on the skin and mucosae (see section 4.8),~~.~~ the use of Optalgin Teva 1g/2ml solution for injection must be stopped immediately and the blood count (including differential count) checked. Do not wait for the results of the laboratory tests before stopping the treatment.

…..

Drug-induced liver damage

Cases of acute hepatitis with a predominantly hepatocellular pattern occurring within a few days to a few months of the start of treatment have been reported in patients treated with metamizole. The signs and symptoms include raised serum levels of liver enzymes with or without jaundice, often in association with other drug hypersensitivity reactions (e.g. rash, blood count abnormalities, fever and eosinophilia) or accompanied by features of autoimmune hepatitis. Most patients recovered after the discontinuation of metamizole treatment. In isolated cases, however, progression to acute liver failure with the need for liver transplantation has been reported.

The mechanism of metamizole-induced liver damage has not been clearly elucidated. However, the data suggest an immunoallergic mechanism.

Patients should be told to consult their doctor if they develop symptoms that suggest liver damage. Treatment with metamizole should be discontinued in such patients and hepatic function checked.

Metamizole should not be administered again if liver damage has previously occurred on treatment with metamizole for which no other cause could be found.

.....

4.5 Interaction with other medicinal products and other forms of interaction

Pharmacokinetic induction of metabolic enzymes:
Dipyrone can induce metabolic enzymes including CYP2B6 and CYP3A4. The concomitant use of dipyrone with bupropion, efavirenz, methadone, valproate, ciclosporin, tacrolimus or sertraline can bring about a reduction in the plasma concentration of these medicinal products, with a potential decrease in clinical efficacy. Caution is therefore required in the case of co-administration with dipyrone; the clinical response and/or active substance levels should be monitored accordingly.
~~Dipyrone can cause a decrease in the plasma ciclosporin level. The latter must therefore be monitored if Optalgin® Teva 1 g/2 ml solution for injection is co-administered.~~

.....

4.8 Undesirable effects

.....

Typical signs of thrombocytopenia include an increased bleeding tendency and petechiae on the skin and mucosae.

.....
Gastrointestinal disorders
Not known: Cases of gastrointestinal bleeding have been reported.

Hepatobiliary disorders
Not known: Drug-induced liver damage including acute hepatitis, jaundice, raised liver enzymes (see section 4.4)

.....

4.9 Overdose

.....

Treatment in cases of overdose:
There is no known specific antidote to dipyrone. If the ingestion of dipyrone has only recently occurred, an attempt can be made to limit absorption into the body through primary detoxification measures (e.g. gastric lavage) or measures to reduce absorption (e.g. activated charcoal). The main metabolite (4-N-methylaminoantipyrine) can be eliminated by haemodialysis, haemofiltration, haemoperfusion or plasma filtration.

.....

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

טבע תעשיות פרמצבטיות בע"מ
רח' התאנה 1, פארק תעשיה חמ"ן ת.ד. 975, שוהם 6085001 |
www.tevapharm.com