אפריל 2025

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 מסומנות ~~בקו חוצה~~):

[...]
4.2 Posology and method of administration
[…]
<u>Duration of administration</u>
The duration of administration depends on the nature and severity of the disorder. ~~In case of prolonged treatment with dipyrone, regular blood counts, including differential blood count, are necessary.~~
[…]

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[…]

4.3 Contraindications

- Hypersensitivity to the active substance or to other pyrazolones or pyrazolidines ~~(this includes patients who are reacted with agranulocytosis, for example, after administration of these substances)~~ or to any of the excipients listed in section 6.1.
- Agranulocytosis in the medical history induced by dypirone, other pyrazolones or pyrazolidines.

[…]

- ~~Disturbances of bone marrow function (e.g. after treatment with cytostatics) or disorders of the haematopoietic system.~~
- Impaired bone marrow function or diseases of the hematopoietic system.

[…]

4.4 Special warnings and precautions for use

Agranulocytosis

Treatment with dypirone can cause agranulocytosis, which may be fatal (see section 4.8). It may occur even after dypirone has previously been used without complications.

Dypirone-induced agranulocytosis is an idiosyncratic adverse reaction. It is not dose-dependent, and may occur at any time during treatment, even shortly after treatment discontinuation.

Patients must be instructed to discontinue their treatment and seek immediate medical attention in case any symptoms suggestive of agranulocytosis appear (e.g. fever, chills, sore throat and painful mucosal changes, especially in the mouth, nose and throat or in the genital or anal region).

If dypirone is taken for ever, some symptoms of emerging agranulocytosis may go unnoticed. Similarly, symptoms may also be masked in patients receiving antibiotic therapy.

If signs and symptoms suggestive of agranulocytosis, a complete blood cell count (including differential blood count) should be performed immediately, and treatment must be stopped while waiting for the results. If confirmed, treatment must not be reintroduced (see section 4.3).

[...]

~~Agranulocytosis~~

~~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).~~

[…]

[…]

4.8 Undesirable effects

[…]

Blood and lymphatic system disorders

[…]

~~There are isolated reports suggesting that the risk of agranulocytosis may possibly be increased if Optalgin® Teva 1 g/2 ml solution for injection is administered for longer than a week.~~

~~This reaction is not dose-dependent and can occur at any time during treatment. It manifests as high fever, shivering, sore throat, swallowing difficulties and inflammation of the mouth, nose, throat, genitals or anal regions. In patients receiving antibiotics, however, these signs may be minimal. Swelling of lymph nodes or the spleen is minor or completely absent. The erythrocyte sedimentation rate is greatly increased and granulocytes are considerably reduced or completely absent. In general, but not always, haemoglobin, erythrocyte and platelet values are normal (see section 4.4).~~

~~Immediate cessation is crucial to recovery. It is therefore urgently recommended to stop Optalgin® Teva 1 g/2 ml solution for injection immediately, without waiting for the laboratory results, if an unexpected deterioration in the patient's general condition occurs, the fever does not subside or recurs, or painful changes occur in the mucosa, especially in the mouth, nose and throat.~~

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

~~If pancytopenia occurs, the treatment must be stopped immediately and the full blood count monitored until it normalises (see section 4.4).~~

[…]

Immune system disorders

[…]

At the first signs of shock such as: e.g. cold sweat, dizziness, dizziness, drowsiness, skin discoloration or problems in the heart area, emergency measures should be taken.

~~Optalgin® Teva 1 g/2 ml solution for injection must therefore be stopped immediately if skin reactions occur.~~

[…]

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