

“פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר". עלון מאושר : אוגוסט 2011
"This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved." Date of approval: August 2011.

Physician's Package Insert

עלון לרופא

OPTALGIN®

אופטלגין®

INJECTION

משכך כאבים: הזרקה לתוך הוריד
מוריד חום: הזרקה לתוך השריר.

Important Note: Parenteral administration of dipyron requires that appropriate facilities for treatment of a possible shock reaction be available.

Composition

Each ampoule of 2 ml contains:

Active Ingredient

Dipyron 1 g

Other Ingredients

Sodium dithionite, sodium carbonate anhydrous, water for injection.

Action

Optalgin Injection is a non-narcotic analgesic and antipyretic, available on physician's prescription only.

Indications

As an Analgesic

Optalgin 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.

Intravenous administration of dipyron should be carried out slowly over a period of at least 5 minutes, followed by reasonable clinical observation.

Intramuscular administration of dipyron for relief of pain is not recommended. However, if medical circumstances require such administration, all due precautions should be exercised to permit reasonable clinical observation.

As an Antipyretic

Optalgin 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.

Contraindications

Known hypersensitivity to dipyron or to pyrazolone derivatives or to any other ingredient of the preparation.

Pregnancy and breastfeeding.

Acute porphyria.

Genetic deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD).

History of blood dyscrasias or acute bone marrow suppression.

Warnings

When using parenteral dipyron, special consideration should be given to the possible risk of life-threatening complications resulting from "shock syndrome".

It should be remembered that the risk of shock is much greater with parenteral administration than with oral administration.

Careful monitoring is warranted in patients with high fever.

Rare cases of agranulocytosis, as a hypersensitivity reaction, have been reported.

The appearance of symptoms indicative of agranulocytosis, such as high fever, pain in throat, buccal ulceration, tiredness, and weakness, warrants immediate discontinuation of the drug, and an urgent blood count determination.

Special caution is required in patients who may be more prone to hypersensitivity reactions, as in patients with bronchial asthma and chronic urticaria.

As with other pyrazolone derivatives, cutaneous allergic reactions may appear such as urticaria and maculopapular eruption. Exceptionally, they may be severe enough and manifested by epidermal necrolysis (Stevens -Johnson syndrome or Lyell's syndrome), in which case immediate discontinuation of treatment is imperative.

Optalgin Injection contains sodium dithionite as an antioxidant preservative. As with other sulfites, sodium dithionite may cause allergic-type reactions in certain susceptible patients, including anaphylactic symptoms and life-threatening, or less severe, asthmatic episodes. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic patients.

Use in Pregnancy and in Breastfeeding

See Contraindications.

Use in Pediatrics

Use of dipyrene is not recommended in infants under 3 months of age or 5 kg/body weight, unless deemed necessary.

Adverse Reactions

The most serious adverse reactions to dipyrene are "shock syndrome", and agranulocytosis (see also Warnings).

Allergic

Anaphylactic shock (see Warnings).

Agranulocytosis has rarely been reported. It is an immuno-allergic adverse reaction lasting at least 1 week. Agranulocytosis is unpredictable, not dose-related and may occur even after a single dose.

Dermatological reactions (see Warnings).

Hematological

Rarely agranulocytosis, anemia, leucopenia and thrombocytopenia, have been reported.

Renal

Isolated cases of acute renal insufficiency or interstitial nephropathy have been reported.

Other

Drowsiness, tiredness, and headache have been reported with dipyrene administration.

Hypotension has been reported following intravenous administration of dipyrene.

Nausea, vomiting, gastric irritation and xerostomia have been described with oral and parenteral dipyrene administration.

Precautions

Careful inquiry should be made concerning previous hypersensitivity reactions of the patients to drugs and food.

Red coloration may appear in urine with acid pH; it may be due to an exceedingly small quantity of a metabolite (rubazonic acid).

Caution should be exercised when dipyron is used in patients with hepatic or renal disorders.

Drug Interactions

Dipyron/ Chlorpromazine: Concurrent use of dipyron and chlorpromazine may cause hypothermia; therefore combined therapy with these two drugs should be avoided.

Dipyron/Cyclosporin: Dipyron may cause a reduction in cyclosporin blood levels, by an unknown mechanism.

Dipyron/ Alcohol: Concurrent administration is not recommended in patients who react to small quantities of alcoholic beverages (flush, lacrimation and sneezing), since these patients may be more prone to allergic reactions to dipyron.

Dipyron/Anticoagulants: Because of possible thrombocytopenia appearing as an adverse reaction of dipyron, caution is required when dipyron is administered to patients on anticoagulant therapy.

Dosage and Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Adults and Adolescents Over 14 Years of Age

Intravenous Administration as an Analgesic

1 g (2 ml), administered by slow injection, up to 4 times daily. In severe pain, 2.5 g (5 ml) may be administered twice daily (the maximum daily dosage is 5 g).

Intramuscular Administration as an Antipyretic

2.5 g (5 ml), to be repeated only if deemed necessary.

Infants and Children

Use of dipyron is not recommended in infants under 3 months of age or 5 kg/body weight.

In infants 3-12 months, Optalgin Injection should be administered by the intramuscular route only. In older children, the injection may be administered by either the intramuscular or intravenous routes.

Dosage guidelines for the administration of Optalgin Injection as an analgesic and/or antipyretic, in infants over 3 months of age and in children, are presented in the table below.

Optalgin Injection - Dosage Guidelines in Infants and Children

Age	Smallest Single Dosage	Maximum Daily Dosage
3-5 months	0.1 ml I.M. only	4 x 0.2 ml
6-11 months	0.1 ml I.M. only	4 x 0.3 ml
1-2 years	0.2 ml I.M./I.V.	4 x 0.4 ml
3-4 years	0.2 ml I.M./I.V.	4 x 0.6 ml
5-7 years	0.4 ml I.M./I.V.	4 x 0.8 ml
8-11 years	0.5 ml I.M./I.V.	4 x 1.0 ml
12-14 years	0.8 ml I.M./I.V.	4 x 1.6 ml

Storage

Store in a cool place, below 25°C.

Drug Registration No.: 026.70.20782.21

Manufacturer

Teva Pharmaceutical Works Private Limited Company,
Hungary

License Holder

Teva Pharmaceutical Industries Ltd.,
P.O.Box 3190, Petach-Tikva