PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The preparation shall be sold without a doctor's prescription

OPTALGIN®

Drops for oral administration

Composition

Each 1 ml (25 drops) contains:
Dipyrone 500 mg
For the list of inactive ingredients in the preparation see section 6 - "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is given without need for a doctor's prescription. You should take the medicine correctly. The drops are not intended for infants weighing less than 5 kg. Consult a pharmacist if you need further information. You should refer to the doctor if the fever lasts for more than 3 days or pain persists for more than 7 days, despite use of the medicine. The risk of agranulocytosis increases if treatment continues for more than 7 days (see "Side Effects" section).

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of moderate to strong pain, such as headache, toothache and menstrual pain, and for lowering high fever that does not respond to other measures of treatment.

Therapeutic group: Optalgin® Drops contain an active ingredient belonging to the pyrazoline group.

2. BEFORE USING THE MEDICINE

☒ Do not use the preparation if:

- Do not use the medicine when you are pregnant or breastfeeding.
- Do not use this medicine if you have a known sensitivity to the active ingredient dipyrone (metamizole), propyphenazone, phenazone, phenylbutazone or to any of the inactive ingredients of the medicine.
- Do not use this medicine for mild pains.
- Do not use this medicine if you have a known deficiency of the G6PD enzyme ("sensitivity to fava beans").
- Do not use if you suffer from a blood system impairment.
- Do not use this medicine if you suffer from acute hepatic porphyria (an inherited disease in which there is increased production and accumulation of porphyrin, causing disorders, for instance of the nervous system).
- Do not use the medicine if you have bone marrow depression (for instance, following chemotherapy).

Special warnings regarding use of the medicine

Inform the doctor before commencing treatment if you are suffering, or have suffered in the past, from:

- A tendency for hypersensitivity to painkillers, medicines for treatment of arthritis and other medicines.
- Allergy related symptoms: in such cases, the risk of anaphylactic shock increases (see "Side Effects" section).
- If you are prone to allergies: such as allergies to food, alcoholic beverages, animals, preservatives, hair dyes, various medicines, allergy that causes asthma or chronic skin rash (urticaria) – Optalgin® should only be taken under medical supervision.
- Impairment in function of the liver, kidney, blood system (e.g., coagulation or anemia).
- If you suffer from diseases that are accompanied by a decrease in white blood cells.
- If you suffer from asthma or chronic respiratory airway infections.

❗ Warnings

Dipyrone may cause rare but life-threatening effects of anaphylactic shock and/or agranulocytosis (see "Side Effects" section).

- Do not use this medicine frequently or for a prolonged period of time without consulting the doctor.
- If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.
- Rarely, hypersensitivity to this medicine may cause leucopenia (too few white blood cells), thrombocytopenia (manifested by an increased tendency to bleed) or agranulocytosis (toxic damage to white blood cells) and shock. This reaction is manifested by high fever, chills, sore throat, difficulty swallowing and inflammation of the mouth cavity, the nose or genitals. When one of these signs occur, and they may already occur in the first hour after taking the medicine, stop taking the medicine immediately and consult the doctor. When consulting the doctor you must inform him if you have taken another medicine concomitantly with Optalgin®.
- This medicine may cause a red color in acidic urine. This effect should not be a cause for concern.

❗ If you are taking, or have recently taken other medicines

including non-prescription medicines, nutritional supplements and vitamins, tell the doctor or pharmacist. You should especially inform the doctor or pharmacist if you are taking or have just finished treatment with a medicine from one of the following groups:

- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin.
- anticoagulants (warfarin).
- ciclosporin (for transplantations) - the ciclosporin level may be reduced.
- chlorpromazine (an antipsychotic medicine).

❗ Use of Optalgin® and food

Take the medicine with a glass of water. It can be taken before or after a meal.

❗ Pregnancy

Do not use this medicine if you are pregnant.

❗ Breastfeeding

Do not breastfeed during treatment with this medicine.

❗ Use in children

This medicine is not intended for infants weighing less than 5 kg.

❗ Driving

Use of this medicine at higher than recommended dosages may affect your reaction time, your ability to drive and to operate machinery. Therefore, avoid driving a vehicle, operating machinery and any other activity requiring alertness. The risk increases if the medicine is taken together with alcohol.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure. The dosage and treatment regimen will be determined by the doctor only.

The usual dosage unless otherwise instructed by the doctor:

Take the appropriate dosage according to the table below.

Take the medicine at intervals of 6-8 hours.

It is recommended that the dosage be given by the weight of the child in accordance with the table. Only if the child's weight is unknown will the dosage be determined by the child's age.

Do not take a dose more than 3 times in 24 hours.

The drops are not intended for infants weighing less than 5 kg.

Do not exceed the recommended dose.

Make sure the bottle cap is tightly closed after use.

If the fever lasts for more than 3 days or pain persists for more than 7 days, despite use of the medicine, refer to the doctor.

The risk of agranulocytosis increases if treatment continues for more than 7 days (see "Side Effects" section).

Adults and adolescents from 15 years of age and above (above 53 kg body weight):

25-50 drops up to 3 times a day.

Infants and children:

Age	Body weight (Kg)	Dosage (No. of drops)
3-11 months	5-8	2-5 drops up to 3 times daily
1-3 years	9-15	4-12 drops up to 3 times daily
4-6 years	16-23	6-19 drops up to 3 times daily
7-9 years	24-30	10-25 drops up to 3 times daily
10-12 years	31-45	12-37 drops up to 3 times daily
13-14 years	46-53	19-44 drops up to 3 times daily

If you accidently took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of medicine with you.

Effects of overdose:

Nausea, vomiting, abdominal pain, impairment of kidney function, and in rarer cases: dizziness, convulsions, unconsciousness, drop in blood pressure, shock, heart rhythm disorders.

When taking a very high dosage of the medicine your urine may turn red.

If you forget to take the medicine: do not take two doses together to make up for a missed dose.

Adhere to the treatment as recommended by the doctor.

4. SIDE EFFECTS

As with any medicine, use of Optalgin® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if you experience:

The main side effects of the medicine are hypersensitivity reactions. They include:

Anaphylactic shock and agranulocytosis. These are rare but life-threatening effects. They can occur even if you took the medicine in the past with no complications. They can already occur in the first hour after taking the medicine, but also a few hours later.

- Anaphylactic shock - an acute hypersensitivity reaction manifested by cold sweat, severe rash all over the body, swelling of the skin or the pharynx, mucosal blisters, dizziness, severe shortness of breath, nausea, vomiting, stomach irritation, rapid pulse, feeling of tightness in the chest and a sharp drop in blood pressure (rare): stop treatment and call for medical help immediately!
  Meanwhile, until the doctor arrives, lay the patient down on his back and raise his legs. It is advisable to warm his body with a blanket.
- Rarely, hypersensitivity to this medicine may cause leucopenia (too few white blood cells), thrombocytopenia (reduction in platelets manifested by an increased tendency for bleeding) or agranulocytosis (toxic damage of the white blood cells). The risk of agranulocytosis increases if the medicine is taken for more than 7 days. This reaction is manifested by high fever, chills, sore throat, difficulty swallowing and inflammation of the mouth cavity, the nose or genitals, worsening of your general condition (such as tiredness or weakness).
  If you are taking antibiotics concomitantly – it is possible that these signs will be weaker. If any of the above signs occurs, stop taking the medicine immediately and consult with the doctor.
- Skin or mucosal effects: In isolated cases there may be:
  Stevens-Johnson syndrome or Lyell's syndrome - these are acute and life-threatening skin reactions including rash or mucosal blisters - stop treatment and refer to the doctor immediately!
- In rare cases, mainly in cases of a drop in blood volume, in patients with a history of kidney diseases and in cases of overdose, there may be: kidney dysfunction, such as reduction in or absence of urinary output, kidney inflammation or secretion of protein into the urine (rare): stop treatment immediately and refer to the doctor!

If a side effect occurs, if any of the side effects worsen, or if you are suffering from side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- **The medicine can be used for up to 3 months after first opening the bottle, but not after the expiry date of the preparation.**

6. FURTHER INFORMATION

In addition to the active ingredient the medicine also contains: water

What does the medicine look like and what are the contents of the package: The medicine comes in two packages: 10 ml and 15 ml. The medicine drops are yellowish in color.

Manufacturer:

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

This leaflet was checked and approved by the Ministry of Health in September 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 020.15.20487.00

OPTA DROP PL SH 160517
34O161034-03