Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

OPTALGIN® DROPS NEW

Oral drops

Active ingredient

Every 1 ml (20 drops) contains: dipyrone 500 mg

For information about inactive ingredients and allergens in this medicine: see section 2 under - 'Important information about some of this medicine's ingredients' and section 6 - 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information.

You must take the medicine correctly. These drops are not intended for babies weighing under 5 kg. Consult your doctor if the fever lasts more than 3 days or pain persists for more than 7 days, despite using the medicine. Optalgin Drops may cause a sharp drop in the count of certain white blood cells (agranulocytosis), which may lead to serious and life-threatening infections (see section 2 'Before using this medicine' and section 4 - 'Side effects').

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for relieving moderate to severe pain, such as headache, toothache, and menstrual pain, and for reducing high fever that does not respond to other treatment measures.

Therapeutic group: pyrazolone class.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient dipyrone (metamizole) or other pyrazolones (such as propyphenazone, phenazone) or pyrazolidines (such as phenylbutazone, oxyphenbutazone).
- You are sensitive (allergic) to benzyl alcohol or any of the other ingredients that this medicine contains (see section 6 - 'Additional information').
- You have previously developed agranulocytosis after using a medicine containing the active ingredient dipyrone, or similar medicines of the group of pyrazolones or pyrazolidines.
- You have a known sensitivity to pain relievers (analgesics asthma syndrome or sensitivity to pain relievers experienced as rash/ angioedema). This applies to patients who react to pain relievers (such as salicylates, paracetamol, diclofenac, ibuprofen, indomethacin, or naproxen) with constriction of the lower airways or other hypersensitivity reactions such as rash with itching and bruising, runny nose and swelling (rash, rhinitis, angioedema).
- Your bone marrow function is impaired, for example after treatment with certain medicines used to treat cancer.
- You have a disorder affecting the production of blood cells.
- You have a hereditary disease which includes a disorder in the production of the color of your red blood cells (acute intermittent hepatic porphyria).

Special warnings regarding use of this medicine

Before treatment with Optalgin, tell your doctor or pharmacist.

Optalgin Drops contains dipyrone and is associated with a rare but life-threatening risk of sudden circulatory failure.

A sharp drop in the count of certain white blood cells (agranulocytosis)

Optalgin may cause a sharp drop in the count of white blood cells called granulocytes (agranulocytosis), which are important for fighting off infections (see section 4 - 'Side effects'). The sharp drop in the white blood cell count (agranulocytosis) may lead to serious and life-threatening infections. Stop treatment with the medicine and see a doctor immediately if you experience any of the following symptoms, which may indicate agranulocytosis: high fever, chills, sore throat, difficulties swallowing and painful sores in mucosal tissues, especially in the mouth, nose, throat and in the genital or anal region. If agranulocytosis is suspected, your doctor will send you for laboratory tests to check your blood count.

If the medicine is given for fever reduction, or if concomitant antibiotic therapy is given, some symptoms of emerging agranulocytosis may be difficult to identify.

Agranulocytosis may develop anytime during treatment with Optalgin and even shortly after stopping treatment. Agranulocytosis may occur even if you have taken the medicine without special problems in the past.

Stop treatment immediately and consult your doctor if you develop signs of reduced counts of different types of blood cells (pancytopenia) (such as feeling generally unwell, inflammation or persistent fever, bruises, bleeding, and pallor) or signs of reduced platelet count (thrombocytopenia) (such as increased tendency to bleed, tiny bleeds under the skin and in mucous membranes) (see section 4 - 'Side effects').

If you develop an allergic reaction to Optalgin, you are at a high risk of developing similar reactions to other pain relievers.

If you develop allergic reactions to Optalgin or other reactions mediated by the immune system (such as agranulocytosis), you are at a high risk of developing similar reactions to other pyrazolones and pyrazolidines (substances that are chemically similar), such as the pain relievers containing phenazone, propyphenazone, phenylbutazone, and oxyphenbutazone.

If you develop an allergic reaction to other pyrazolones and pyrazolidines or to other pain relievers, or if you get another reaction mediated by the immune system, you are at a high risk of developing a similar reaction to Optalgin.

Severe hypersensitivity reactions

If you have any of the following effects, your risk of severe hypersensitivity reactions to Optalgin is significantly increased:

- sensitivity to pain-relief and anti-rheumatic medicines that is experienced as itchy rash and bruising or swelling. If this happens, do not take Optalgin. For additional information, see section 2 under - 'Do not use this medicine if'.
- attacks of breathlessness caused, for example, by asthma, particularly if you also have nasal polyps or a nose and sinus inflammation.
- chronic rash (urticaria).
- hypersensitivity to coloring agents (such as tartrazine) or preservatives (such as benzoates).
- sensitivity to alcohol experienced as sneezing, watery eyes, and severe flushing in the face which develop after consuming even small amounts of alcohol. This kind of sensitivity to alcohol may be a sign of an as-yet undiagnosed sensitivity to pain relievers (see section 2 under - 'Do not use this medicine if').

Patients at increased risk of hypersensitivity reactions, should only use Optalgin after the doctor has carefully weighed the potential risks against the expected benefits (see also section 2, under - 'Do not use this medicine if').

If Optalgin is used in such cases, patients should be placed under close medical supervision, with emergency facilities available.

Anaphylactic shock may occur, particularly in susceptible patients (see section 4 - 'Side effects'). Special care is needed in patients with asthma or a tendency to develop hypersensitivity reactions.

Serious skin reactions

Serious skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (called **DRESS**)- have been reported following dipyrone therapy. If you experience one or more of the symptoms of serious skin reactions described in section 4 ('Side effects'), stop taking Optalgin and seek medical attention immediately.

If you have ever experienced severe skin reactions, you must never resume treatment with Optalgin (see section 4 - 'Side effects').

Liver function problems

There are reports of liver inflammation in patients taking dipyrone who developed symptoms within a few days to a few months of starting treatment.

Stop taking Optalgin and consult your doctor if you develop symptoms of liver function problems, such as:

nausea or vomiting, fever, tiredness, loss of appetite, dark urine, pale stools, yellowing of the skin or the whites of the eyes, itching, rash, or upper abdominal pain. Your doctor will check your liver function in these cases.

Do not take Optalgin if you have ever taken a medicine containing dipyrone and developed liver function problems.

Drop in blood pressure

Optalgin can cause a drop in blood pressure (see section 4 - 'Side effects').

This risk is increased if you:

- have low blood pressure
- are severely dehydrated, have poor blood circulation, or are in the early stages of circulatory failure (for example, following a heart attack or severe injuries)
- have a high fever.

The doctor will carefully consider the use of Optalgin, will monitor the patient closely, and will take preventive measures (such as circulatory stabilization) to reduce the risk of a drop in blood pressure.

Optalgin may only be used with careful monitoring of your blood circulation, when avoiding a drop in blood pressure is necessary. For example in case of:

- severe coronary heart disease
- constriction that blocks blood flow in the vessels that supply blood to the brain.

Impaired kidney or liver function

In case of impaired kidney or liver function, you may take Optalgin only after your doctor has carefully evaluated the risks and the benefits and has taken suitable precautions (see section 3, under - 'Patients with impaired kidney or liver function').

Children and adolescents

This medicine is not intended for babies weighing less than 5 kg. See the dosage table by weight and age in section 3.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially if you are taking:

Medicines whose blood level and/or efficacy may be reduced:

- Bupropion: used to treat depression and to stop smoking.
- Efavirenz, a medicine used to treat HIV/AIDS.
- Methadone, a medicine used to treat severe pain or withdrawal from addiction to narcotic substances.
- Valproate, a medicine used to treat epilepsy or bipolar disorder.
- Cyclosporine, a medicine used to suppress the immune system.
- Tacrolimus, a medicine used to prevent organ rejection in patients with transplants.
- Sertraline, a medicine used to treat depression.

Your doctor will monitor efficacy and/or medicine blood levels, if taken at the same time.

Medicines that affect or can be affected by Optalgin levels:

- Methotrexate, a medicine used to treat cancer and rheumatic diseases - If given at the same time, the potential of methotrexate to damage blood formation may be increased, especially in elderly patients. This combination should therefore be avoided.
- Acetylsalicylic acid (aspirin) - If you take low-dose acetylsalicylic acid to protect your heart, Optalgin may reduce the effect of aspirin on your platelets.
- Chlorpromazine, a medicine used to treat mental disorders - Using Optalgin at the same time may cause a serious fall in your body temperature.

Pyrazolones (the group of medicines to which Optalgin belongs) can interact with certain medicines:

- Medicines to prevent blood clotting
- Captopril, a medicine for high blood pressure and certain heart disorders
- Lithium, a medicine used to treat mental disorders
- Diuretics such as triamterene
- Medicines for lowering blood pressure

It is not known to what extent Optalgin causes these interactions between medicines.

Effect on lab tests

Tell your doctor that you are taking Optalgin before you have lab tests because the active ingredient dipyrone can affect the results of certain tests (for example, blood levels of creatinine, fats, HDL cholesterol, or uric acid). Take the medicine only after providing the blood sample for these tests.

Using Optalgin Drops and alcohol consumption

It is advisable to avoid drinking any alcohol while taking Optalgin.

Using Optalgin Drops and food

It is best to take the drops with water. You can take Optalgin before or after a meal.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy

Only use during pregnancy after consulting your doctor, and only after your doctor has conducted a thorough risk-benefit assessment.

In the third trimester (after week 28) you may use Optalgin only in the lowest effective dose.

After week 28: Do not take more than three grams (120 drops) a day, and for no more than 3-4 days in a row.

Breastfeeding

The breakdown products of dipyrone pass into breast milk.

While you are breastfeeding you may use Optalgin only if you do not respond to paracetamol or ibuprofen.

Driving and using machines

This medicine is not known to affect the ability to concentrate and react when used within the recommended dose range. However, as a precaution, at least at higher doses, you should bear in mind that your ability to concentrate and react may be affected, so avoid using machines, driving, or other hazardous activities, particularly if you have been drinking alcohol.

Important information about some of this medicine's ingredients

One mg of this medicine contains 37.5 mg sodium (the main ingredient of table salt). This amount is equivalent to 1.9% of the recommended maximum daily intake of sodium for an adult.

Propylene glycol: This medicine contains approximately 10 mg propylene glycol per 1 ml. Consult your doctor before giving this medicine to babies under 4 weeks old, particularly if the baby is receiving another medicine that contains propylene glycol or alcohol.

Benzyl alcohol: This medicine contains approximately 0.2 mg benzyl alcohol per 1 ml.

Benzyl alcohol may cause serious side effects including breathing problems in infants and young children.

Do not use this medicine in newborns (up to 4 weeks) unless recommended by your doctor.

Do not use this medicine for longer than one week in babies and young children (under 3 years old) unless recommended by your doctor or pharmacist.

Consult your doctor or pharmacist if you are pregnant or breastfeeding or if you have a liver or kidney disease, because large amounts of benzyl alcohol may build up in your body and cause side effects (called 'metabolic acidosis').

3. HOW TO USE THIS MEDICINE?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Your dose will be determined based on the severity of the pain or fever and depending on your individual response to Optalgin. Dose can be determined by the patient's age or weight. Take the lowest effective dose.

In the absence of other directions from your doctor, the recommended dose is:

- Take the correct dose as shown in the table below. Take the medicine at intervals of 6-8 hours.
- It is advisable to dose children by weight according to the table. You may determine the dose by the child's age, only if you do not know the child's weight.
- Do not take more than three doses in 24 hours.
- **These drops are not intended for babies weighing less than 5 kg.**

Adults and adolescents over 15 years old (weighing over 53 kg):

20-40 drops, up to 3 times a day.

Babies and children:

Age	Body weight (kg)	Dose (number of drops)
3-11 months	5-8	2-4 drops, up to 3 times a day
1-3 years	9-15	3-10 drops, up to 3 times a day
4-6 years	16-23	5-15 drops, up to 3 times a day
7-9 years	24-30	8-20 drops, up to 3 times a day
10-12 years	31-45	10-30 drops, up to 3 times a day
13-14 years	46-53	15-35 drops, up to 3 times a day

Consult your doctor if the fever lasts more than 3 days or pain persists for more than 7 days, despite using the medicine.

Elderly patients, patients in poor general health, or patients with impaired kidney function

Reduce the dose because the elimination of Optalgin breakdown products may be delayed.

Patients with impaired kidney or liver function

Repeated high doses should be avoided, as the elimination rate is reduced when kidney or liver function is impaired. It is not necessary to reduce the dose if only used for a short time. There is no experience with long-term use.

Do not exceed the recommended dose.

How to use the medicine

These drops are for oral administration only. It is recommended to take the drops with water. You can take this medicine before or after a meal. Make sure the cap is closed securely after using.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Signs of overdose include:

nausea, vomiting, abdominal pain, reduced kidney function to the extent of acute kidney failure, dizziness, drowsiness, loss of consciousness, convulsions, sharp drop in blood pressure to the extent of circulatory failure, fast heart rhythm.

If you suspect an overdose, tell your doctor immediately so suitable measures can be applied.

Note: After very high doses of this medicine, excretion of a harmless breakdown product of dipyrone may turn the urine red.

If you forget to take the medicine, do not take a double dose to make up for the missed dose.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Optalgin Drops may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following side effects may have serious and even life-threatening consequences; stop taking Optalgin Drops immediately and consult a doctor as soon as possible. You may need immediate treatment:

- **Hypersensitivity reactions** - rare side effects (may affect up to 1 in 1,000 patients)
  Signs of milder reactions include:
  burning sensation in the eyes, cough, runny nose, sneezing, tightness in the chest, skin redness (especially in the face and head area), rash (hives) and facial swelling, and less commonly nausea and abdominal cramps.
  Special warning symptoms include burning, itching and flushing sensation on and under the tongue and, in particular, on the palms of the hands and soles of the feet.
  Such milder reactions may develop into more serious forms, including: severe rash, severe angioedema (swelling, also in the throat area), severe bronchospasm (crampy narrowing of the lower airways), fast heartbeat (sometimes also a slow heartbeat), heart-rhythm disorders, a sharp drop in blood pressure, sometimes also with a previous increase in blood pressure, unconsciousness, and circulatory failure.
  In patients with analgesics asthma syndrome, hypersensitivity reactions are usually experienced as asthma attacks (see section 2 - 'Do not use this medicine if').
- **Serious skin reactions:**
  Stop using the medicine and seek medical attention immediately if you notice any of the following side effects:
  - reddish, flat, target-like or circular patches on the upper part of the body, often with a central blister, peeling skin, ulcers in the mouth, throat, nose, genitals and eyes. These serious rashes may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis) - rare side effects (may affect up to 1 in 1,000 patients).
  - widespread rash, high fever and enlarged lymph nodes (**DRESS** syndrome or drug hypersensitivity syndrome) – side effects of unknown frequency (the frequency cannot be estimated from the available data).
- **Severe changes in blood cell count:**
  - **Agranulocytosis** (severe reduction in the count of certain white blood cells) with signs such as unexpected deterioration of your general condition (e.g. fever, chills, sore throat, difficulty swallowing), a fever that does not subside or recurs or mucosal pain, mainly in the mouth, nose, throat or genital and anal area. Very rare side effects (may affect up to 1 in 10,000 patients).
  - **Thrombocytopenia** (reduction in platelet count), with signs such as increased bleeding tendency and bruising (small red spots on the skin and mucosa caused by bleeding). Very rare side effects (may affect up to 1 in 10,000 patients).
  - **Pancytopenia** (severe reduction in several types of blood cells), which can cause weakness, bruising or make infections more likely. Side effects of unknown frequency (the frequency cannot be estimated from the available data).

  Your doctor will send you for blood tests. Do not take Optalgin until the laboratory test results are available and your doctor clearly recommends continuation of use of this medicine.
- Nausea or vomiting, fever, tiredness, loss of appetite, dark urine, pale stools, yellowing of the skin or the whites of the eyes, itching, rash, or upper abdominal pain. These symptoms may be signs of **liver injury**. Unknown frequency (the frequency cannot be estimated from the available data). See also section 2 - 'Special warnings regarding use of this medicine'.

Additional side effects

Uncommon side effects (may affect up to 1 in 100 patients):

- Purple to deep red rash, sometimes with blisters (fixed drug eruption).
- Sharp drop in blood pressure, which may be a direct effect of the medicine and is not accompanied by other signs of a hypersensitivity reaction. Such a reaction only rarely leads to a severe drop in blood pressure. The risk of a drop in blood pressure may be increased in case of abnormally high fever.
  Typical symptoms of a sharp drop in blood pressure are rapid heartbeat, pallor, trembling, dizziness, nausea, and fainting.

Rare side effects (may affect up to 1 in 1,000 patients):

- Reduction in the number of white blood cells (**leukopenia**).
- **Skin rash** (such as maculopapular exanthema).

Very rare side effects (may affect up to 1 in 10,000 patients):

- **Asthma attack**
- **Acute deterioration in kidney function**, in some cases with abnormally little or no urine, excretion of blood proteins in the urine (proteinuria) or progression to acute renal failure, **kidney inflammation** (acute interstitial nephritis).

Side effects of unknown frequency (the frequency cannot be estimated from the available data):

- Sudden circulatory failure caused by an acute allergic reaction (anaphylactic shock)
- **Heart attack caused by an allergic reaction** (Kounis syndrome)
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness with concomitant disturbance of bone marrow function (**aplastic anemia**).
- **Gastrointestinal bleeding.**
- **Liver inflammation**, yellowing of the skin and whites of the eyes, increase in liver enzymes in the blood.

A harmless breakdown product of dipyrone may turn the **urine red**.

Benzyl alcohol can cause an allergic reaction.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' found on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight 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 use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- **Use this medicine within 6 months of first opening the bottle, but no later than the expiry date listed on the package.**

6. Additional information

In addition to the active ingredient, this medicine also contains:

Saccharine sodium, sodium cyclamate, raspberry flavor (contains nature-identical flavoring substances, benzyl alcohol, flavoring preparations, propylene glycol), cream flavor (contains nature-identical flavoring substances, triacetin, propylene glycol, benzyl alcohol), citric acid monohydrate, sodium hydroxide, purified water.

What the medicine looks like and contents of the package:

A clear, slightly yellow to yellow-green solution in a glass bottle.

Available in packs of 10 ml, 20 ml, 50 ml, and 100 ml. Not all package sizes may be marketed.

Name and address of the license holder and manufacturer: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

This leaflet was revised in May 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 164-35-35644-00.

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