

Patient package insert in accordance with
the pharmacist's regulations (preparations)1986
This medicine is sold without prescription

V-Dalgin Drops For oral use

Composition: Each 1 ml (20 drops) contains: Dipyron 500 mg
For inactive ingredients preparation see section 6 - "more information."
Carefully read the package leaflet before using this medicine.
This leaflet contains concise information on this medicine.
If you have additional questions, contact your doctor or pharmacist.
This medicine is given without prescription. You must take the medicine correctly.

The drops are not for babies weighing less than - 5 kg. Consult your pharmacist if you need more information.
You should contact your doctor if the fever lasts more than 3 days or pain persists more than 7 days despite the treatment. Risk of agranulocytosis increases if treatment continues beyond 7 days. (See the side effects section).

V-Dalgin drops- contain active substance belonging to the chemical family Pyrazolones.

1. What is the medicine for?

The medicine is designed to relieve moderate to strong pain such as headaches, teeth, menstrual cramps and high fever with no response to other treatment measures.

2. Before using this medication

Do not use this medicine:

- If you are pregnant or breastfeeding.
- If you are hypersensitive to the active ingredient Dipyron (Metamizol), Propyphenazone, Phenazone, Phenylbutazone or any of the other inactive ingredient of this medicine.
- For minor ailments.
- If you know of a deficiency of the enzyme G6PD ("Faba beans Sensitivity").
- If you suffer from impaired blood system.
- If you suffer from the acute hepatic porphyria (a hereditary disease in which there is increased production and accumulation of porphyrin, causing nervous system disorders for example).
- If there is a suppression of the bone marrow (such as after treatment with chemotherapy).

Special warnings concerning the use of this medicine:

Consult your doctor before starting treatment if you suffer or have suffered in the past from:

- Tendency for hypersensitivity to painkillers and medicines for treating arthritis and other medicines.
- Allergy symptoms: In these cases, the risk of anaphylactic shock increases (see the side effects section).
- If you suffer from a tendency to allergies: such as food allergy, alcoholic beverages, animals, preservatives, hair dyes and different medications, allergy that causes asthma or chronic skin rash (urticaria) – V-dalgin should be taken only under medical supervision.
- Abnormalities of Liver function, kidney, circulatory system (such as clotting or anemia).
- If you suffer from diseases causing decreased white blood cells.
- If you suffer from asthma or chronic infections of the respiratory tract.

Warnings: Dipyron may cause rare but life-threatening anaphylactic shock and or agranulocytosis. (See the side effects section).

Do not use this medicine frequently or for prolonged periods without consulting a doctor.

If you are sensitive to any food or medicine, inform your doctor before taking this medicine.

Hypersensitivity to this medicine may cause rarely leucopenia (decreased white blood cells count), thrombocytopenia (expressed in bleeding tendency) or agranulocytosis (toxic damage to white blood cells) and shock. This response is manifested by high fever, chills, sore throat, difficulties in swallowing, and inflammation of the oral cavity, nose or genitals. With the advent of these signs, which may appear early as the first hour after taking the medication, stop taking the medicine immediately and consult your doctor. You must also inform your doctor, if you have been taking concurrently any other medicine with V-dalgin.

This medicine may cause a red color in acidic urine. This should not be a concern.

If you take, or have taken recently other medicines including non-prescription medicines and dietary supplements or vitamins, tell your doctor or pharmacist. In particular, inform your doctor or pharmacist if you are taking or if you have just finished treatment with medication of the following groups:

- Non steroidal Anti-inflammatory medicines (NSAIDS) such as aspirin.
- Anticoagulants (warfarin).
- Cyclosporine (for Transplants) - may decrease the level of cyclosporine.
- Chlorpromazine (anti - psychotic drug).

Using V-dalgin and food: Take this medicine with a glass of water, can be taken before or after a meal.

Pregnancy: Do not use this medication if you are pregnant.

Nursing: 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 doses than recommended may impair reaction time, the ability to drive and operate machinery and therefore these activities should be avoided, while using at higher doses. The risk increases if the medicine is taken with alcohol.

3. How to use this medicine?

Always use this medication by your doctor instructions. You should check with your doctor or pharmacist if you are unsure.

Recommended dosage unless otherwise prescribed:

Take the appropriate dose as shown in the table below.

Take the medicine at intervals of 6-8 hours.

It is recommended to give the dose by weight child according to the table. Only in the case of unknown weight of the child - will determine the

dosage according to age of the child.

Do not take the dose more than three times at 24 hours.

The drops are not for babies weighing less than - 5 kg.

Do not exceed the recommended dose.

If the fever lasts more than 3 days or pain persists more than 7 days despite the treatment, contact your doctor. Risk of agranulocytosis increase if treatment continues beyond 7 days. (See the side effects section).

Adults and adolescents aged 15 years and older (over body weight of 53 kg): 20-40 drops up to 3 times a day.

Infants and children:

Age	Body weight (kg)	Dose (number drops)
3-11 months	5-8	2-4 drops 3 times a day
1-3 years	9-15	3-10 drops 3 times a day
4-6 years	16-23	5-15 drops 3 times a day
7-9 years	24-30	8-20 drops 3 times a day
10-12 years	31-45	10-30 drops 3 times a day
13-14 years	46-53	15-35 drops 3 times a day
Adults and adolescents over Age 15 years;	Above 53	20-40 drops 3 times a day

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

Effects of overdose:

Nausea, vomiting, abdominal pain, kidney dysfunction, and more rarely: dizziness, convulsions, unconsciousness, decreased blood pressure, shock, arrhythmias.

Taking very high doses of the medicine, urine may turn red.

If you forget to take the medication: Do not take two doses together to make up the missed dose.

Continue the treatment as recommended by your doctor.

4. Side Effects

Like all medicines, the use of V-dalgin may cause side effects in some users. Do not panic reading list of side effects. You might not suffer from any of them.

Consult a doctor immediately if you experience:

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

Anaphylactic shock and agranulocytosis. These are rare but life-threatening. They can occur even if in the past you have taken the medicine without complications. They can occur in the first hour after taking the medication, but also several hours afterwards.

- Anaphylactic shock - a phenomenon of hypersensitivity strongly expressed in a cold sweat, severe rash all over the body, swelling of the skin or throat, blisters in the mucosal tissues, dizziness, shortness of breath, nausea, vomiting, stomach irritation, rapid pulse, feeling of tightness in the chest and a sharp drop in blood pressure (Rare): Stop the treatment and call medical help immediately!

Meanwhile, until the arrival of the doctor one should put the patient on his back, lift his feet and warm him up by a blanket.

- Hypersensitivity to this medicine may cause rarely leucopenia (decreased white blood cells), thrombocytopenia (expressed in bleeding tendency) or agranulocytosis (toxic damage to white blood cells).

Risk of agranulocytosis increases when the medicine is taken for more than seven days. This response has the expression of high fever, chills, sore throat, difficulties in swallowing, and inflammation in the oral cavity, nose or genitals. Deterioration in general health (such as fatigue or weakness). If you are taking in parallel antibiotics - these signs may be weaker.

With the appearance of these symptoms, stop taking the medicine immediately and consult your doctor.

- Skin or mucosal tissues: in a few cases you may suffer from: Stevens-Johnson syndrome or Lyell's syndrome - these are skin reactions severe and life-threatening, such as a rash or blisters in mucosal tissues - Stop treatment and contact your doctor immediately!

- In rare cases, particularly in situations of decreased blood volume in patients with a history of renal disease and in cases of overdose, there might be: Renal dysfunction such as decreased or lack of urination, kidney inflammation or urinary protein excretion (Rare): stop treatment immediately and contact the doctor!

If any of the side effects gets worse, or if you suffer side effects not mentioned in the leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by selecting the link "Report of side effects due to medication" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects, or by accessing the URL:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@mo.gov.il>

5. How to store your medicine

Avoid poisoning! This medicine and other medicines must be kept out of the reach of children and / or infants, to avoid poisoning. **Do not induce vomiting without a direct order from a doctor. Do not take medicines in the dark!** Check the label and the dose **each time** you take the medicine. Wear glasses if you need them.

Do not use after the expiration date (exp. date) shown on the packaging. Expiry date refers to the last day of that month.

Store below 25°C.

May be used up to 6 months from first opening.

6. More information

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

How this medicine looks and the contents of the package: Brown glass vial containing a yellow aqueous solution. Sticky dripping bottle top and a white plastic cover over it.

Manufacturer and registration holder: Vitamed Pharmaceutical Industries Ltd., P.O.B. 114, Binyamina 3055002 Israel.

Registration Number: 659 128 293

This leaflet has been examined and approved by the Ministry of Health on 04-2012