

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**  
This medicine is dispensed without a doctor's prescription

## Paramoli Drops Suspension

### Active ingredient

Each 1 ml contains 100 mg paracetamol

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.

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

Consult your doctor if the fever persists for more than 3 days or if the symptoms do not resolve within 5 days despite use of the medicine.

### 1. What is this medicine intended for?

This medicine is intended to relieve pain and reduce fever.

**Therapeutic group:** analgesic and antipyretic.

### 2. Before using this medicine

**Do not use this medicine if:**

- you have a known sensitivity to paracetamol or to any of the other ingredients in this medicine (see section 6).
- the patient has severe hemolytic anemia (a disease caused by destruction of red blood cells).
- the patient has severe liver disease (severe liver failure).

### Special warnings about using this medicine

Consult a doctor or pharmacist before treatment with Paramoli Drops.

Use with caution if the patient:

- has bulimia (an eating disorder that involves episodes of binge eating followed by purging efforts)
- has cachexia (a condition characterized by extreme thinness, reduced muscle mass, and thinning of the skin caused by a chronic illness)
- is on an unbalanced diet for a long time (chronic malnutrition)
- is dehydrated (severe loss of water/fluids from the body)
- has low blood volume (hypovolemia)
- has liver diseases that impair liver function (liver damage, jaundice, Gilbert's syndrome)
- is concomitantly taking medicines that affect liver function (see 'Interactions with other medicines' below, in this section)
- has G6PD deficiency (a substance normally present in the body and whose shortage can cause a blood disorder)
- has hemolytic anemia (a disease caused by destruction of red blood cells)

Use at high doses and/or for prolonged periods

Using this medicine at high doses and/or for prolonged periods can cause liver disorders (liver disease), kidney disorders, and changes in the blood, some of which are severe. When used this way, the doctor will perform tests to monitor liver and kidney function and blood composition over time. Before using the medicine in children, inform the doctor if the child has any liver or kidney disorders.

### Tests and follow-up

The administration of paracetamol can interfere with the determination of uricemia and glycemia in blood tests.

### Interactions with other medicines

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

- **Medicines containing paracetamol.** While using paracetamol, before giving any medicine to a child, check that it does not contain paracetamol in order to avoid high doses of paracetamol, which can cause severe side effects.
- **Medicines that slow the emptying of the stomach** (such as anticholinergic medicines, opioids) - delay the effect of Paramoli Drops.
- **Medicines that accelerates emptying of the stomach** (such as prokinetics) - speed up the effect of Paramoli Drops.
- **Cholestyramine** (medicine for reducing cholesterol in the blood) - reduces the effect of paracetamol.
- **Chloramphenicol** (an antibiotic) - may increase the risk of side effects.
- **Medicines for blood clotting.** When used at the same time as paracetamol, especially with prolonged treatment and high doses of paracetamol (4 grams per day for at least 4 days), Paramoli Drops should be given only under close medical supervision.
- **Medicines or preparations that change liver function during chronic treatment,** such as:
  - rifampicin (an antibiotic).
  - cimetidine (a medicine for treatment of stomach ulcers).
  - anti-epileptic medicines such as glutethimide, phenobarbital, or carbamazepine.
  - zidovudine (a medicine for treatment of HIV).
  - flucloxacillin (an antibiotic), due to the serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) which requires urgent treatment and which may occur especially in cases of severe kidney impairment, sepsis (when bacteria and their toxins penetrate the blood and cause organ damage), malnutrition, chronic alcoholism and when the maximum daily dosage of paracetamol is used.

Using these medicines together with Paramoli Drops requires close medical supervision.

### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult a doctor before you start using this medicine.

### Children and adolescents

Parents must tell their child's doctor about any side effects and other medicines given to their child.

### Important information about some of this medicine's ingredients

Each 1 ml of this medicine contains 399 mg **sorbitol**. Sorbitol is a source of fructose. If there is a known intolerance to certain sugars, or a diagnosis of hereditary fructose intolerance (a rare genetic disease in which a person is unable to break down fructose), consult your doctor before taking this medicine (you or your child). Sorbitol can cause gastrointestinal discomfort and mild laxative effect.

Each 1 ml of this medicine contains 2.3 mg **propylene glycol**. Consult your doctor or pharmacist before giving this medicine to newborns under four weeks old, particularly if the baby is receiving other medicines that contain propylene glycol or alcohol.

Each 1 ml of this medicine contains 1 mg of **sodium benzoate**. Sodium benzoate can increase jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks old).

This medicine contains less than 23 mg of sodium per 1 ml, and is therefore considered sodium-free.

### 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.

The generally accepted dose is:

Children

Find the suitable dosage in the following tables.

This medicine can be given from the age of 0 and weight of at least 3 kg.

For babies who weigh less than 3 kg, consult your doctor.

If you know the child's weight - find the dosage in the weight table, which shows dosage according to weight.

Only if the child's weight is not known - the dosage will be determined according to age, as shown in the age table, which shows dosage according to age only.

### Weight table

Dosage according to the child's weight is calculated as 15 mg/kg of the child's weight per dose. In other words, 0.15 ml for every kg of the child's body weight.

| Child's weight  | mg  | Dose in ml | Maximum number of doses per 24 hours |
|---|-----|------------|--------------------------------------|
| For babies who weigh less than 3 kg, consult your doctor. |     |            |                                      |
| 3 kg  | 45  | 0.45       | up to 5 times                        |
| 4 kg  | 60  | 0.60       | up to 5 times                        |
| 5 kg  | 75  | 0.75       | up to 5 times                        |
| 6 kg  | 90  | 0.90       | up to 5 times                        |
| 7 kg  | 105 | 1.05       | up to 5 times                        |
| 8 kg  | 120 | 1.20       | up to 5 times                        |
| 9 kg  | 135 | 1.35       | up to 5 times                        |
| 10 kg   | 150 | 1.50       | up to 5 times                        |
| 11 kg   | 165 | 1.65       | up to 5 times                        |
| 12 kg   | 180 | 1.80       | up to 5 times                        |
| 13 kg   | 195 | 1.95       | up to 5 times                        |
| 14 kg   | 210 | 2.10       | up to 5 times                        |
| 15 kg   | 225 | 2.25       | up to 5 times                        |
| 16 kg   | 240 | 2.40       | up to 5 times                        |
| 17 kg   | 255 | 2.55       | up to 5 times                        |
| 18 kg   | 270 | 2.70       | up to 5 times                        |
| 19 kg   | 285 | 2.85       | up to 5 times                        |
| 20 kg   | 300 | 3.00       | up to 5 times                        |
| 21 kg   | 315 | 3.15       | up to 5 times                        |
| 22 kg   | 330 | 3.30       | up to 5 times                        |
| 23 kg   | 345 | 3.45       | up to 5 times                        |
| 24 kg   | 360 | 3.60       | up to 5 times                        |
| 25 kg   | 375 | 3.75       | up to 5 times                        |
| 26 kg   | 390 | 3.90       | up to 5 times                        |
| 27 kg   | 405 | 4.05       | up to 5 times                        |
| 28 kg   | 420 | 4.20       | up to 5 times                        |
| 29 kg   | 435 | 4.35       | up to 5 times                        |
| 30 kg   | 450 | 4.50       | up to 5 times                        |

### Age table

If the child's weight is unknown:

Children the same age can have very different weights, so an effort must be made to find the child's weight and determine their dosage according to the weight table.

Only if it is impossible to find out the child's weight - the dosage can be determined according to the age table.

| Child's age | Dose in ml | Maximum number of doses per 24 hours |
|-------------|------------|--------------------------------------|
| 0–3 months  | 0.40       | up to 5 times                        |
| 4–11 months | 0.80       | up to 5 times                        |
| 1–2 years   | 1.20       | up to 5 times                        |
| 2–3 years   | 1.60       | up to 5 times                        |
| 4–5 years   | 2.40       | up to 5 times                        |

Doses should be taken/given at intervals of at least 4 hours, as necessary, up to 5 doses in 24 hours.

**Do not exceed the recommended dose.**

**Contact your doctor if the fever persists for more than 3 days or if the symptoms do not resolve within 5 days despite use of the medicine.**

### Method of use:

Be sure to measure the dose with a measuring syringe.

1. Shake well before use.
2. Find the required amount in the dosage table, in the "Dose in ml" column.
3. Filling the syringe:

| Paramoli Drops 15 ml                       | Paramoli Drops 50 ml  |
|--|---|
| Fill the syringe with the required amount. | a. Insert the syringe into the opening in the bottle neck adaptor.  |
|  | b. To fill the syringe, turn the bottle upside-down. With the syringe held in place, pull the plunger gently downwards to draw the medicine to the appropriate mark on the syringe. |
|  | c. Turn the bottle right-side up again and gently remove the syringe from the bottle opening.   |

4. Empty the contents of the syringe slowly into the child's mouth, onto the inside of their cheek.
5. Thoroughly rinse the syringe parts with lukewarm water after each use, and dry well.
  - Do not place the syringe parts in a domestic sterilizer or dishwasher. Do not heat the syringe in the microwave (with or without medicine).
6. After drying, store the syringe inside the medicine's cardboard box.

- Keep the syringe out of the reach of children. Do not bite on the syringe.
- Do not leave medicine inside the dosing syringe for a long time. The syringe is intended to come into contact with the medicine only while measuring and giving the medicine.

With liquid medicines, use the syringe or dropper intended for measuring the correct amount of medicine. If a measuring device is not included in the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine.

Household teaspoons vary in size and you may not receive the

correct amount of medicine.

**If you or your child has 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. Do not induce vomiting unless explicitly instructed to do so by your doctor!

Symptoms of overdose

If very high doses of paracetamol are taken, the symptoms that you/ your child may experience during the first 12-48 hours include:

- loss of or decreased appetite
- nausea
- vomiting
- significant deterioration in general condition
- severe liver damage (hepatic cytolysis) which can lead to the liver not being able to fulfill its function (liver failure), increased production of acids related to metabolism (metabolic acidosis), and brain damage (encephalopathy)
- changes in blood indicators in lab tests (high levels of transaminases, lactate dehydrogenase, and bilirubin in the blood, reduced prothrombin levels in the blood).

Taking excessive amounts of paracetamol increases the risk of toxicity and can lead to death, especially in cases where the patient:

- has liver disease
- has chronic alcoholism
- is on an unbalanced diet for a long time (chronic malnutrition)
- is taking other medicines or preparations that increase liver function.

**If you forget to take this medicine at the scheduled time,** 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 Paramoli Drops may cause side effects, such as dizziness, in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**Stop using the medicine and contact a doctor immediately if you experience:**

**Allergic reactions** with:

- redness of the skin accompanied by itching (hives)
- swelling of the throat
- swelling of the hands, feet, ankles, face, lips, tongue, and/or throat (angioedema)
- severe allergic reactions (anaphylactic shock)

### Additional side effects of unknown frequency

Effects involving the blood

- reduced platelet count (thrombocytopenia)
- reduced white blood cell count (leukopenia/agranulocytosis)
- reduced hemoglobin, the substance responsible for transporting oxygen in the blood (anemia)

Effects involving the nervous system

- vertigo

Effects involving the stomach and digestive system

- stomach and bowel disorders

Effects involving the liver

- impaired liver function
- inflammation of the liver (hepatitis)

Effects involving the skin and tissue under the skin

- red spots, blisters with areas of skin detachment, blisters, skin rash (erythema multiforme, Stevens-Johnson syndrome, toxic

epidermal necrolysis).

Severe skin reactions have been reported very rarely.

Effects involving the kidneys and urinary tract

- impaired kidney function (acute kidney failure)
- kidney inflammation
- blood in the urine
- producing less urine or none

**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.**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can use this link: <https://sideeffects.health.gov.il>

You can also report side effects by email to [safety@trima.co.il](mailto:safety@trima.co.il).

### 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

### Storage conditions

Store at a temperature below 25°C.

Paramoli Drops 15 ml in a glass bottle may be used for up to 3 months after first opening.

Paramoli Drops 15 ml in a plastic bottle may be used up to 6 months after first opening.

Paramoli Drops 50 ml may be used up to 6 months after first opening.

### 6. Additional information

**In addition to the active ingredient, this medicine also contains:** sorbitol solution 70%, glycerin, masker bitter SC753612, poloxamer 188, strawberry flavour SC753611[propylene glycol (E1520), acetic acid (E260), natural flavouring substances and preparations], xanthan gum, sodium benzoate, FD&C Red No. 40, citric acid anhydrous, purified water.

**What the medicine looks like and contents of the pack:**

A glass bottle containing 15 ml or a plastic bottle containing 15/50 ml of a pale pink to pink suspension. 15 ml packs contain a 1.5 ml syringe and 50 ml packs contain a 5 ml syringe. The bottle is closed with a child-resistant closure. Not all pack sizes may be marketed.

**Manufacturer and registration holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot, 4023000, Israel.

Revised in July 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 178-92-38124-99

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