

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Tiptipot Novimol®

Suspension
Each 1 ml contains 100 mg paracetamol



Inactive ingredients and allergens in the preparation - see section 6 - "Additional information" and the "Important information about some ingredients of the medicine" section. **Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you have further questions.

Refer to the 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 the medicine intended for?

The medicine is intended to relieve pain and reduce fever.

Therapeutic class: analgesic and antipyretic.

2. Before using the medicine:

Do not use this medicine if:

- There is a known sensitivity to paracetamol or to any of the other ingredients the medicine contains (see section 6).

Special warnings regarding the use of the medicine:

- If you developed skin side effects in the past as a result of taking preparations containing paracetamol, do not take preparations containing paracetamol, so that severe skin side effects will not recur.
- The preparation contains paracetamol, which may cause liver damage when:

- Given at a higher dosage than recommended or for a prolonged period of time.
- Alcoholic beverages are consumed during the course of treatment.
- Additional medicines which affect liver function are taken.
- In patients with glutathione deficiency, use of paracetamol may increase the risk for metabolic acidosis.
- Do not use this medicine frequently without consulting the doctor.
- Do not take additional antipyretics and analgesics or cold medicines without consulting a doctor or a pharmacist, to prevent paracetamol overdose or poisoning.
- Do not take other medicines from the same family and/or other preparations containing paracetamol.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.
- Consult a doctor regarding use of this medicine in children under 3 years of age.
- Consult a doctor about using this preparation or another preparation for pain relief and/or to reduce fever.
- Preparations that stimulate production of enzymes in the liver (e.g. rifampicin, barbiturates).
- Medicines for epilepsy - phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory drugs.
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems).
- Medicines that reduce the stomach emptying rate (e.g., propantheline, anticholinergic antidepressants and narcotic analgesics) will compromise the absorption of paracetamol.
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).
- Cholestyramine (for reduction of excess blood lipids).
- Other analgesics or antipyretics and anti-arthritis medicines.

Use of paracetamol and alcohol consumption:

During treatment with paracetamol, do not consume alcohol due to increased risk of liver damage.

Pregnancy, breastfeeding and fertility:

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

Use in children:

Parents must report to the treating doctor all side effects and any additional medicine given to the child.

Important information about some ingredients of the medicine:

This medicine contains 140 mg of sorbitol in each 1 ml. Sorbitol is a source of fructose. If there is a known intolerance to certain sugars, or a diagnosis of hereditary fructose intolerance, consult with your doctor before taking this medicine.

This medicine contains 1 mg of sodium benzoate in each 1 ml.

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

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The generally accepted dosage is:

Children

Find the suitable dosage in the following tables.

If you know the child's weight - find the dosage in the weight table indicating 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 indicating dosage according to the child's age only.

Weight table
The 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.

Age table
In case the child's weight is unknown: Children of identical ages can be of significantly different weights. Therefore, an effort must be made to find out the child's weight and determine the 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 weight | mg | Dose in ml | Maximum number of doses per 24 hours |
|----------------|-----|------------|--------------------------------------|
| 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

In case the child's weight is unknown: Children of identical ages can be of significantly different weights. Therefore, an effort must be made to find out the child's weight and determine the 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.

With liquid medicines, use the syringe or dropper intended for measuring the proper 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 it is likely you will not receive the correct amount of medicine.

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

Doses should be taken/administered in intervals of at least 4 hours, as necessary, up to 5 doses in 24 hours. **Do not exceed the recommended dose.**

Refer to the 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 the included syringe. Shake well before use.

1. Find the required amount in the dosage table, in the "Dose in ml" column.
2. Filling the syringe **Novimol 15 ml**
Fill the syringe with the required amount.

Novimol 50 ml

a. Insert the syringe into the opening in the bottle's neck.

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 up to the appropriate mark on the syringe.

c. Turn the bottle upside-down again (right side up) and gently remove the syringe from the bottle's opening.

3. Empty the contents of the syringe slowly into the child's mouth, towards the inner wall of the cheek.

4. Wash the two parts of the syringe well with lukewarm water.

With liquid medicines, use the syringe or dropper intended for measuring the proper 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 it is likely you will not receive the correct amount of medicine.

If you or your child took an overdose or if a child accidentally swallowed this medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor! Even if you feel well/the child feels well, immediate treatment is essential, due to the risk of developing severe liver damage.

Side effects can be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, swelling, increased sweating, pain or tenderness in the upper abdomen, and they may not reflect the severity of liver damage.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine.

Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, use of Tiptipot

Novimol may cause side effects, such as dizziness, in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Severe side effects:

Stop using this medicine and refer to a doctor immediately if:

- Severe allergic reactions occur, such as rash, itching, swelling of the face, lips, tongue, throat and/or extremities that can cause difficulty breathing or swallowing.

Paracetamol may, in rare cases, cause the appearance of severe skin diseases whose symptoms can be: redness, rash, blisters, widespread skin damage. Severe skin side effects may appear even if you had no problems in the past taking preparations containing the active ingredient paracetamol.

If skin side effects appear, discontinue treatment and refer to a doctor immediately.

- Signs of changes in the blood system occur, such as: bleeding, bruises, development of infections more easily.

Additional very rare side effects - side effects that occur in less than one out of 10,000 users: Bronchospasm, liver failure, thrombocytopenia (low platelets).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp.) appearing on the package. The expiry date refers to the last day of that month.

Storage:

Store at a temperature lower than 25°C.

Novimol 15 ml may be used up to 6 months after the first opening. Novimol 50 ml may be used up to the expiration date.

6. Additional information

In addition to the active ingredient, the medicine also contains: Sorbitol Solution 70%, Glycerol, Xanthan Gum, Sucralose, Strawberry Cream Flavour, Sodium Benzoate, Citric acid, FD&C Red No. 40, Purified Water.

What does the medicine look like and what are the contents of the package:
A glass bottle containing 15 ml or 50 ml of a pink-red suspension with white particles, with a strawberry fragrance.

Manufacturer and license holder:
CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi 83057 Israel.

This leaflet was revised in 03/2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 134613137

