

**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 section 2 – "Important information about some of the ingredients of the medicine".

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 need further information.

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)
- The patient suffers from severe hemolytic anemia (a disease caused by the destruction of red blood cells)
- The patient suffers from severe liver disease (severe liver failure)

Special warnings regarding the use of the medicine:

Consult a doctor or pharmacist before treatment with Tiptipot Novimol. Use with caution in cases in which the patient:

- Suffers from bulimia (an eating disorder which involves episodes of binge eating followed by purging efforts)
- Suffers from cachexia (a condition characterized by extreme thinness, reduced muscle mass and thinning of the skin caused by a chronic illness)
- Follows an unbalanced diet for a long time (chronic malnutrition)
- Is dehydrated (severe loss of water/fluids in the body)
- Suffers from low blood volume (hypovolemia)
- Suffers from liver diseases that impair liver function (liver damage, jaundice, Gilbert's syndrome)
- Concomitantly takes medicines that affect liver function (see "Drug interactions" below in this section)

- Suffers from G6PD deficiency (a substance normally present in the body, a shortage of which can cause a blood disorder)
- Suffers from hemolytic anemia (a disease caused by the destruction of red blood cells)

While using the medicine, inform the doctor straight away in case of severe illness, including severe kidney impairment or sepsis (when bacteria and their toxins penetrate into the bloodstream leading to organ damage), malnutrition, chronic alcoholism or if you are taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in the situations listed when paracetamol is used at regular doses for prolonged periods or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: severe breathing difficulties with deep and rapid breathing, tiredness, nausea and vomiting.

Important information about some of the 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 medicine.

Drug interactions:

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

Medicines containing paracetamol.

While using paracetamol, before giving the child any medicine, check that it does not contain paracetamol, in order to avoid high doses of paracetamol which can cause severe side effects.

Medicines which slow the emptying of the stomach (such as anticholinergic medicines, opioids) – delay the effect of Tiptipot Novimol.

Medicines which accelerate the emptying of the stomach (such as prokinetics) – accelerate the effect of Tiptipot Novimol.

Cholestyramine (a medicine for reducing cholesterol in the blood) – reduces the effect of paracetamol.

Chloramphenicol (an antibiotic) – may increase the risk of side effects.

Medicines against blood clotting.

When these are being used, especially in case of prolonged treatment and high doses of paracetamol (4 grams per day for at least 4 days), Tiptipot Novimol can be given only under strict 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

Using these medicines together with Tiptipot Novimol requires close medical supervision.

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.

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Novimol 15 ml
Fill the syringe with the required amount.

Novimol 50 ml

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

Stop using the medicine and refer to 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 with unknown frequency:

Effects involving the blood

- Decrease in blood platelet count (thrombocytopenia)
- Decrease in 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 subcutaneous tissue

- 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 kidney and urinary tract

Impaired kidney function (acute kidney failure)

Kidney inflammation

Blood in the urine

Reduced or cessation of urine production

Side effects with unknown frequency (effects whose frequency has not yet been determined)

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

Suffers from liver disease

Suffers from chronic alcoholism

Follows an unbalanced diet for a long time (chronic malnutrition)

Is taking other medicines or preparations that increase liver function

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 the 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 via 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 (Expi) indicated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store at a temperature below 25 °C.

Novimol 15 ml may be used for 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 suspension with white particles, with a strawberry fragrance.

Manufacturer and licensee: CTCS Chemical Industries Ltd, 3 Haikma st, Kiryat Malach 30357 Israel.

This leaflet was revised in 1/2025 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1-3461117

