

**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.

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 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.

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.

Child's weight

mg

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

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

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.
- Turn the bottle upside-down again (right side up) and gently remove the syringe from the bottle's opening.
- Empty the contents of the syringe slowly into the child's mouth, towards the inner wall of the cheek.

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

4. With liquid medicines, use the syringe or dropper intended for measuring the correct amount of medicine.

5. Effects involving the blood

- Decrease in blood platelet count (thrombocytopenia)
- Decrease in white blood cell count (leukopenia/ agranulocytosis)

6. Effects involving the nervous system

7. Effects involving the stomach and digestive system

8. Effects involving the liver

9. Effects involving the skin and subcutaneous tissue

10. Effects involving the kidney and urinary tract

11. Severe skin reactions have been reported very rarely.

12. Side effects with unknown frequency

13. Effects involving the kidney and urinary tract

14. Impaired kidney function (acute kidney failure)

15. Kidney inflammation

16. Blood in the urine

17. Reduced or cessation of urine production

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