



# STOPALGIC® 10 mg/ml, solution for infusion

## Paracetamol

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects that are not listed in this leaflet. See section 4.

### What is in this leaflet?

1. What is STOPALGIC 10 mg/ml, solution for infusion and in which case is it used?
2. What you need to know before you use STOPALGIC 10 mg/ml, solution for infusion?
3. How to use STOPALGIC 10 mg/ml, solution for infusion?
4. What are the possible side effects?
5. How to store STOPALGIC 10 mg/ml, solution for infusion?
6. Contents of the packaging and other information
1. WHAT IS STOPALGIC 10 mg/ml, solution for infusion AND IN WHICH CASE IS IT USED?

Pharmacotherapeutic group: OTHER ANALGESICS AND ANTIPYRETICS, ATC code: N02BE01

This medication is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

**Vial of 100 mL:** reserved for adults, adolescents and children weighing more than 33 kg.

**Vial of 50 mL:** suitable for full-term newborns, infants and children under 33 kg.

It is indicated in the short-term treatment of moderate pain, especially in the post-operative period, and in the short-term treatment of fever.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE STOPALGIC 10 mg/ml, solution for infusion?**

**Never use STOPALGIC 10 mg/ml, solution for infusion:**

- If you are allergic (hypersensitive) to paracetamol or any of the other ingredients of STOPALGIC, listed in section 6.
- If you are allergic (hypersensitive) to propacetamol (another analgesic for infusion, precursor of paracetamol).
- If you have severe liver disease.

**Warnings and precautions**

Talk to your doctor or pharmacist before using STOPALGIC 10 mg/ml, solution for infusion.

**Take special care with STOPALGIC 10 mg/ml, solution for infusion**

- Use suitable analgesic treatment orally whenever this route of administration is possible.
- In case of liver or kidney disease, or alcohol abuse.
- If you are taking other medicines (including prescription and over-the-counter medicines) containing paracetamol.
- If you are taking other medicines (including prescription and over-the-counter medicines) containing paracetamol.
- In case of nutrition problem (malnutrition).
- In case of glucose-6-phosphate dehydrogenase deficiency (which can cause hemolytic anemia, a blood disease).

Before starting treatment tell your doctor if any of the above mentioned cases apply to you.

**Children and adolescents**

Not applicable.

**Other medicines and STOPALGIC 10 mg/ml, solution for infusion**

This medicine contains paracetamol: it is necessary to take this into account when taking other medicines based on paracetamol or propacetamol, so as not to exceed the recommended daily dose (see following section). Tell your doctor or pharmacist if you are taking other medicines containing paracetamol or propacetamol.

In case of concomitant treatment with probenecid, a reduction in the dose of STOPALGIC should be considered.

Tell your doctor or pharmacist if you are taking oral anticoagulants. Closer monitoring of the anticoagulant effect may be necessary.

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, tell your doctor or pharmacist.

**STOPALGIC 10 mg/ml, solution for infusion with food and drinks**

Not applicable.

**Pregnancy and breast feeding**

**Pregnancy**

Tell your doctor if you are pregnant. STOPALGIC can be used during pregnancy, but the doctor must then assess the appropriateness of the treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

**Breast feeding**

STOPALGIC can be used during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

**If you are pregnant or breastfeeding, think you may be pregnant or are planning to get pregnant, ask your doctor or pharmacist for advice before using this medicine.**

**Driving and using machines.**

Not applicable.

**STOPALGIC 10 mg/ml, solution for infusion contains sodium.**

This medicine contains less than 1 mmol sodium (23 mg) per 100 mL STOPALGIC; so it is considered to be sodium free.

**3. HOW TO USE STOPALGIC 10 mg/ml, solution for infusion?**

STOPALGIC 10 mg/ml, solution for infusion will be given to you by a healthcare professional by injection into your vein.

The dosage will be adjusted individually by your doctor, depending on your weight and your general conditions.

If you have the impression that the effect of STOPALGIC 10 mg/ml, solution for infusion is too strong or too weak, talk to your doctor.

**If you use more STOPALGIC 10 mg/ml, solution for infusion than you should:**

Immediately consult your doctor or pharmacist.

In overdoses, symptoms usually appear within the first 24 hours and include: nausea, vomiting, anorexia, pallor, abdominal pain and a risk of liver damage.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

**If you forget to use STOPALGIC 10 mg/ml, solution for infusion**

Not applicable.

**If you stop using STOPALGIC 10 mg/ml, solution for infusion**

Not applicable.

**4. WHAT ARE THE POSSIBLE SIDE EFFECTS?**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Frequent cases of pain and burning sensation at the injection site have been reported.
- In rare cases (more than 1 in 10,000 and less than 1 in 1,000), you may experience discomfort, a drop in blood pressure or biological changes; abnormally high level of liver enzymes, found during a blood test. In this case, tell your doctor so as to make a subsequent check of the blood test.
- In very rare cases (less than 1 in 10,000 people, including isolated cases), a severe rash or serious allergic reaction may occur (in the form of anaphylactic shock, urticaria, erythema). Stop treatment immediately and tell your doctor.
- In very rare cases, other biological changes requiring a control of the blood tests have been observed: abnormally low levels of certain elements of the blood (platelets, white blood cells) which can result in bleeding from the nose or gums. In this case, tell your doctor.
- Very rare cases of serious skin reactions have been reported. Stop treatment immediately and tell your doctor.
- Cases of redness of the skin, flushing, itching, abnormal increase in heart rate have been reported.

If you get any side effects, talk to your doctor or pharmacist. This also applies to any side effect that is not mentioned in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE STOPALGIC 10 mg/ml, solution for infusion?**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiration date refers to the last day of this month.

Do not store above 30 °C. Do not store in the refrigerator, do not freeze.  
For the 50 mL vial, after dilution in 0.9% sodium chloride or 5% glucose; do not store more than one hour (including the infusion time).  
Before any administration, the product must be visually checked. Do not use STOPALGIC if you notice particles or yellowing.

For single use.  
The product should be used immediately after opening. Any unused solution should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to dispose of the medicines you no longer use. These measures will help protect the environment.

**6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION**

What STOPALGIC 10 mg/ml, solution for infusion contains

• The active substance is:

Paracetamol..... 10.00 mg

For 1 mL.

A vial of 100 mL contains 1000 mg of paracetamol.

A vial of 50 mL contains 500 mg of paracetamol.

• The other ingredients are: Mannitol, cysteine hydrochloride monohydrate, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, water for injections.

What STOPALGIC 10 mg/ml, solution for infusion looks like and contents of the outer package?

STOPALGIC 10 mg/ml is in the form of a solution for infusion in colorless type II glass vials.

Vial of 50 mL: box of 01 vial and box of 12 vials.

Vial of 100 mL: box of 01 vial and box of 12 vials.

**Prescription and delivery condition: No list**

M.A.N°:

STOPALGIC 10mg/mL, box of 01 vial of 100mL : 923 375 2

STOPALGIC 10mg/mL, box of 12 vials of 100mL : 923 375 6

STOPALGIC 10mg/mL, box of 01 vial of 50mL : 923 375 4

STOPALGIC 10mg/mL, box of 12 vials of 50mL : 923 375 5

Marketing authorization holder and manufacturer

Les Laboratoires Médis

Tunis road - KM 7 - BP 206 - 8000 Nabeul - Tunisia

Phone : (216) 72 23 50 06. Fax: (216) 72 23 50 16.

E-mail : contact@labomedis.com

The last date on which this leaflet was revised is 12/2019

**Other**

The following information is intended exclusively for healthcare professionals:

**Intravenous route.**

Vial of 100 mL: reserved for adults, adolescents and children weighing more than 33 kg.

Vial of 50 mL: suitable for full-term newborns, infants and children under 33 kg.

For 50 mL and 100 mL vial, close monitoring is necessary at the end of the infusion.

**Posology**

The dosage is calculated based on the patient's weight (see dosage table below).

**This is a medicine**

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, Don't increase the doses without doctor's advice.

**Keep the medicines out of reach of children**



N°00009  
V01