

# 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).

**Therapeutic indications**  
 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.
  - Your kidney, or alcohol abuse.
  - 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 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 breast-feeding, 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 tell 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 as this may require 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.

**Reporting side effects**  
 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, sodium 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.

What STOPALGIC 10 mg/ml, solution for infusion contains

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**

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**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).

Patient weight	Dose per administration	Volume by administration	Maximum volume per administration based on the group's weight upper limits (mL)**	Maximum Daily Dose ***
< 10 kg *	7.5 mg/kg	0.75 mL/kg	7.5 mL	30 mg/kg
> 10 kg à < 33kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg without exceeding 2g
> 33 kg à < 50kg	15 mg/kg	1.5 mL/kg	75 mL	60 mg/kg without exceeding 3g
> 50 kg with risk factors for hepatotoxicity	1g	100 mL	100 mL	3 g
> 50 kg without risk factors for hepatotoxicity	1g	100 mL	100 mL	4 g

\* **Premature newborns:** There are no efficacy and safety data available in premature newborns.

\*\* Patients with a lower weight should receive smaller volumes.

The interval between two administrations is at least 4 hours. Do not administer more than 4 doses per 24 hours.

The interval between two administrations in severe renal insufficiency is at least 6 hours.

\*\*\* **Maximum daily dose:** The maximum daily dose as presented in the table above is intended for patients not receiving other products containing paracetamol and should be adjusted accordingly, taking into account these products.

**Renal insufficiency**

In patients with renal impairment, the minimum interval between each administration should be changed according to the following schedule:

Creatinine clearance	Administration interval
Clcr ≥50 mL/min	4 hours
Clcr 10-50 mL/min	6 hours
Clcr <10 mL/min	8 hours

**Hepatic insufficiency**

In patients with chronic liver failure or compensated acute liver disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration, Gilbert's disease, weighing less than 50 kg:

The maximum daily dose should not exceed 3 g.

There is no contraindication to the use of paracetamol in therapeutic doses in patients with stable chronic liver disease.

**Elderly patients**

No dosage adjustment is usually necessary in geriatric patients.

**Administration mode**

**RISK OF MEDICATION ERRORS**

Take care to avoid errors in administered dose due to confusion between milligrams (mg) and milliliters (mL), which can lead to accidental overdose which can be fatal.

Paracetamol solution is administered as a 15-minute intravenous infusion.

Patients with a weight ≤ 10 kg.

• The STOPALGIC® glass vial should not be used directly as an infusion, given the small volume of the drug to be administered in this population.

• The volume to be administered must be taken from the vial and can be administered as is or diluted (in a volume ranging from 1 to 9) in 0.9% sodium chloride solution or 5% glucose solution and administered in 15 minutes.

• A 5 or 10 mL syringe should be used to measure the appropriate dose based on the child's weight and the volume to be withdrawn. However, this volume should never exceed 7.5 mL.

• The user should refer to the dosage recommendations in the summary of product characteristics.

**For 50 ml and 100 ml vial**, use a 0.8 mm diameter needle (21 gauges) and pierce the stopper vertically in the place specifically designated.

Originally, the paracetamol solution can be diluted in 0.9% sodium chloride or 5% glucose (in a volume ranging from 1 to 9).

The diluted solution should be visually checked and should not be used in the presence of opalescence, visible particles or a precipitate.

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 your 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



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