

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

SANMOL® Infusion
Paracetamol

Read this entire leaflet carefully before you starts using this medicine because it contains important information for you.

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

What is in this leaflet

1. What SANMOL® Infusion is and what it is used for
2. What you need to know before you use SANMOL® Infusion
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What SANMOL® Infusion is and what it is used for
SANMOL® Infusion contains paracetamol 10mg/ml is used as an analgesic (relieves pain) and an antipyretic (lowers fever)

It is used for :

- short term treatment of moderate pain, especially following surgery.
- short-term treatment of fever.

What you need to know before you use SANMOL® Infusion

Do not use SANMOL® Infusion :

- If you are allergic (hypersensitive) to paracetamol or any of the other ingredients of paracetamol 10mg/ml Solution for Infusion. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you are allergic (hypersensitive) to proparacetamol (another analgesic similar to paracetamol)
- Suffer from severe liver disease

Take special care with SANMOL® Infusion

- Use a suitable oral pain killer as soon as possible
- If you suffer from a liver disease, severe kidney disease or from alcohol abuse
- If you are taking other medicines containing paracetamol
- In cases of nutrition problems (malnutrition) or dehydration.

Inform your doctor before treatment if any of the above mentioned conditions apply to you.

Other medicines and SANMOL® Infusion

Please tell your doctor, nurse, pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products. Take particular

cares if you are taking the following medicines while under treatment with SANMOL® Infusion:

- Other paracetamol-containing products, in order not to exceed the recommended daily dose.
- Probenecid
- Oral anticoagulants. More check-ups to look at the effect of the anticoagulant might be needed

Pregnancy, breast-feeding and fertility

Inform your doctor or nurse if you are pregnant, may be pregnant or are breast feeding. SANMOL® Infusion may be used during pregnancy, however, the doctor must evaluate if the treatment is advisable. Ask your doctor, nurse or pharmacist for advice before taking any medicine

Important information about some of the ingredients of SANMOL® Infusion

This medicinal product contains 4.32 mmol sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

How to use SANMOL® Infusion

For intravenous use (injection into a vein)

The 100ml vial is restricted to adults, adolescents and children weighing more than 33kg.

Dosage

Do not give anything else containing paracetamol while using this medicine.

The dose you will be given will be decided by the doctor and will depend on your weight, liver and kidney function.

The minimum interval between each administration must be at least 4 hours

The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.

No more than 4 doses to be given in 24 hours.

In patients weighing 50 kg or less with risk factors, you will be given a maximum dose of 3g per day

If you are given more SANMOL® Infusion than you should

Talk to a doctor at once if you are given too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Contact your doctor, nurse or pharmacist immediately if you experience the following symptoms of an overdose within the first 24 hours; feeling or being sick, weight loss, pale skin (pallor) or abdominal pain.

If you forget to use SANMOL® Infusion

If you forget to use **SANMOL® Infusion**, pain or fever is likely to return. Do not take a double dose to make up for forgotten individual doses.

If you have any further question on the use of **SANMOL® Infusion**, ask your doctor, nurse or pharmacist

Possible side effects

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

Contact your doctor or nurse and stop treatment immediately if you experience an allergic reaction with symptoms such as swelling of the face, lips, tongue and throat, difficulty breathing or swallowing or a skin rash

Tell your doctor or nurse if you experience the following side effects:

Rare (occurs in less than 1 in 1,000 patients):

- A general feeling of being unwell (malaise)
- A drop in blood pressure
- Changes in liver enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.

Very rare (occurs in less than 1 in 10,000 patients):

- Very rare cases of serious skin reactions have been reported

Not Known (cannot be estimated from available data):

- Other changes in laboratory test results which may result in regular blood checks; abnormally low levels of some types of blood cells (platelets, white cells) can occur, possibly leading to bleeding from the nose or gums

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse, this includes any possible side effects not listed in this leaflet.

How to store SANMOL® Infusion

- Keep this medicine out of the sight and reach of children.
- The doctor and hospital pharmacist are responsible for storing, using and disposing of SANMOL® Infusion correctly.
- Store SANMOL® Infusion at temperature below 30°C. Do not freeze.
- Do not use SANMOL® Infusion after the expiry date which is stated on the carton after EXP.

Contents of the pack and other information

What SANMOL® Infusion contains

The active substance is paracetamol. There is 1000 mg of paracetamol in 100 mL

The other ingredients are sodium metabisulfite, mannitol, L-histidine, sodium hydroxide, Hydrochloric acid and water for Injection

What SANMOL® Infusion looks like and contents of the pack

SANMOL® Infusion is a clear, colorless and odorless solution that is packed in a clear bottle @ 100 mL

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:

PT Sanbe Farma
Jl. Tamansari No. 10
Bandung – Indonesia

Manufacturer:

PT Sanbe Farma (Unit 3)
Jl. Industri Cimareme No. 8
Desa Cimareme, Kecamatan Ngamprah
Kabupaten Bandung Barat - INDONESIA

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