

PATIENT INFORMATION LEAFLET (PIL)

SANFOTAX - 1000

Cefotaxime for Injection USP 1000 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What SANFOTAX - 1000 is and what it is used for
2. Before you take SANFOTAX - 1000
3. How to take SANFOTAX - 1000
4. Possible side effects
5. How to store SANFOTAX - 1000
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1. WHAT SANFOTAX - 1000 IS AND WHAT IT IS USED FOR

Sanfotax-1000 is used to treat bacterial infections including those of the chest (respiratory tract infections), the bladder and urethra (the tube which carries urine from the bladder), the blood (septicaemia), skin and tissues, bone and joints and genital tract in women, including infections which occur, pre, post and during pregnancy. Sanfotax-1000 is also active against a type of sexually transmitted disease called gonorrhoea. Sanfotax-1000 can also be used to treat other infections, such as meningitis.

Sanfotax-1000 may be given to you prior to surgery to reduce the incidence of postoperative infections.

2. BEFORE YOU TAKE SANFOTAX - 1000

Do not use SANFOTAX - 1000:

- if you are allergic to Cefotaxime or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to certain other antibiotics (e.g. penicillins)

Take special care with SANFOTAX-1000

- if you are allergic to Sanfotax - 1000 or any other antibiotic.
- if you are allergic to lidocaine and you are to be given Sanfotax - 1000 as an injection into a muscle
- if you have a previous history of allergies or asthma
- if you have ever had colitis (inflammation of the bowels)
- if you have kidney problems
- if you are on a sodium controlled diet
- if your treatment lasts longer than 7 days, your doctor will need to carry out blood tests.

Taking other medicines:

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Sanfotax-1000 may interfere with other medicines that you may be taking, such as diuretics (used to increase the flow of urine), probenecid and aminoglycoside antibiotics (used to treat infections).

In some cases your doctor will arrange further monitoring, but this is routine and nothing to worry about.

If you require any tests, blood, urine or diagnostic, whilst taking this medicine please ensure the doctor or nurse knows that you are taking Sanfotax-1000.

Pregnancy and Breast-feeding:**Pregnancy**

Ask your health care provider for advice before taking Sanfotax - 1000.

Breast-feeding

Ask your health care provider for advice before taking Sanfotax - 1000.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines:

Do not drive or operate machinery because in individual cases, when administered in high doses, cramp, muscle spasms and giddiness have occurred.

Important information about some of the ingredients of SANFOTAX - 1000:

The sodium content should be taken into consideration if you are on a sodium controlled diet.

3. HOW TO TAKE SANFOTAX - 1000

This medicine will always be given to you by a doctor or nurse. This is because it needs to be given either as an injection or by a drip. In adults, Sanfotax-1000 will normally be given twice daily, however in children and neonates Sanfotax-1000 is normally given in 2-4 divided doses.

If Sanfotax-1000 is used as an injection it should be diluted as the following:

1g of cefotaxime as cefotaxime sodium, the active ingredient, in 4ml of solution for injection into a vein or muscle.

If Sanfotax-1000 is used as an infusion it contains a concentration of 1g of cefotaxime as cefotaxime sodium, the active ingredient, in 40–100ml of solution.

Your doctor will have prescribed the dose of the medicine which is correct for you, depending on the type of infection and any other illnesses you may have. If you ask the person giving you the medicine they will tell you how much and how often you have been prescribed it by your doctor.

If you take more Sanfotax - 1000 than you should:

It is most unlikely that you will be given too much medicine by the nurse or doctor. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. Always ask if you are not sure why you are getting a dose of medicine.

If you think you have missed an injection

Your doctor or nurse have instructions when to give you your medicine. It is most unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose then talk to your nurse or doctor. It is important that the course of treatment your doctor has prescribed is taken. You may start to feel better but it is important not to stop taking this medicine, until the doctor advises, otherwise your condition may get worse again.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sanfotax - 1000 can have side effects, although not everybody gets them.

You may develop a skin rash or itchy skin, a fever, thrush, a furry tongue, kidney problems which may cause pain in your kidney region, tummy upsets, slight sickness or diarrhoea. If the diarrhoea gets very bad, Sanfotax-1000 treatment should be stopped and other medicines will be given to you to stop the diarrhoea. You may also develop weakness, shortness of breath, lethargy, and confusion: these can be signs of acute renal failure.

People may sometimes develop severe allergic reactions, such as breathing difficulties which will require treatment immediately or swelling of the neck, face or throat. If you experience this you should call a doctor or nurse urgently.

If you suffer from a severe rash with or without lesions around the mouth, contact a doctor immediately.

Sanfotax-1000 may sometimes affect your blood, although this is very unusual. It may cause you to feel tired or generally unwell. If you take the medicine for more than 10 days, your doctor may ask you to take a blood test, but this is just routine and nothing to worry about.

If Sanfotax-1000 is given as an injection some people find it slightly painful where the injection has been given. Sanfotax-1000 may also cause your veins to swell following intravenous injection.

Sanfotax-1000 may cause injury to your liver, this may make you feel tired or unwell. You may also have fever and yellowing of the skin or yellowing of the whites of your eyes.

If you feel your heart flutter, contact your doctor immediately.

If you start to move abnormally, suffer from sudden, involuntary muscle contractions or you begin to lose consciousness, you must call a doctor urgently. These are symptoms of encephalopathy.

If you think you are reacting badly in any of these or any other ways to your medicine, talk to your nurse or doctor straight away.

You may also develop a skin rash associated with fever.

Rarely, you may develop a headache, or feel that your head hurts. You should mention this to your doctor or nurse as they may need to give you more treatment for this. You may also feel dizzy.

If any of the side effects gets serious, or if you notice any side effects listed in this leaflet, please tell your health care provider.

5. HOW TO STORE SANFOTAX - 1000

Keep Sanfotax - 1000 out of the reach and sight of children.

Do not store above 30°C. The vial should be kept in the outer carton in order to protect from light.

Do not use Sanfotax - 1000 after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What SANFOTAX - 1000 contains

The active pharmaceutical ingredient is Cefotaxime sodium.

What SANFOTAX - 1000 looks like and contents of the pack

Type III 10 ml vial, sealed with Grey butylated Rubber Stopper and Blue coloured Flip-off seal containing Cefotaxime sodium, equivalent to 1g Cefotaxime.

One vial is packed in a monocarton along with Sterile Water for Injection USP.

Marketing Authorization Holder:

BLISS GVS PHARMA LTD.

102, Hyde Park, Saki Vihar road, Andheri (E), Mumbai – 400 072.

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