PACKAGE LEAFLET: INFORMATION FOR THE USER Suprax 200mg Tablets

Cefixime

sanofi aventis

Is this leaflet hard to see or read? Phone 01483 505515 for help



Read all of this leaflet carefully before taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

- 1. What Suprax is and what it is used for
- 2. Before you take Suprax
- 3. How to take Suprax
- 4. Possible side effects
- 5. How to store Suprax
- 6. Further information

1. What Suprax is and what it is used for

Suprax 200mg Tablets (called Suprax in this leaflet) contains a medicine called cefixime. This belongs to a group of antibiotics called 'cephalosporins'.

Suprax is used to treat infections caused by bacteria. These include infections of the:

- Ear
- Nose, sinuses (such as sinusitis)
- · Throat (such as tonsillitis, pharyngitis)
- Chest and lungs (such as bronchitis, pneumonia)
- Urinary system (such as cystitis and kidney infections)

Before you take Suprax



x You are allergic (hypersensitive) to cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine (see Section 6: Further information).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.

Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or your pharmacist before taking Suprax.

Take special care with Suprax

Check with your doctor or your pharmacist before taking this medicine if:

▲ You have ever had colitis

You have kidney problemsThe person taking this medicine is a child

under the age of 10
If you are not sure if any of the above apply to
you, talk to your doctor or pharmacist before taking
this medicine.

Taking other medicines

Please tell your doctor or your pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Suprax can affect the way some other medicines work. Also some medicines can affect the way Suprax works.

In particular, tell your doctor if you are taking the following:

• Medicines to thin the blood such as warfarin

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if • You are pregnant, might become pregnant or

think you may be pregnant

• You are breast-feeding or planning to breast feed Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast feeding.

Tests

If you require any tests (such as blood or urine tests) while taking this medicine, please make sure your doctor knows that you are taking Suprax.

3. How to take Suprax

Taking this medicine

Always use Suprax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth

Swallow tablets whole with a drink of water

 If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Carefully read the label from the pharmacist. Ask your pharmacist if you are not sure about the dose to take. The medicine should be taken for the prescribed number of days.

How much to take

The usual dose is:

Adults, Elderly and Children over 10 years or weighing more than 50kg

1-2 tablets each day given as a single or divided dose

People with kidney problems

 Your doctor may prescribe a lower dose Children under 10 years old

Suprax Paediatric should be used instead

If you take more Suprax than you should If you have too much of this medicine, talk to your doctor straight away.



If you forget to take Suprax

If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

If you stop taking Suprax

Do not stop taking this medicine without talking to your doctor. You should not stop taking Suprax just because you feel better. This is because the infection may come back or get worse again.



If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor straight away or go to the nearest hospital casualty department if you notice any of the following serious side effects – vou may need urgent medical treatment:

 You have an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue

 Blistering or bleeding of the skin around the lips. eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome.

 Severe blistering r\u00e1sh where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolvsis

 You háve a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'

 You get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine

 You bruise or bleed more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine

Stop taking this medicine and contact your doctor without delay if you get:

· Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'Pseudomembranous colitis'

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days

Feeling sick (nausea) or being sick (vomiting)

Stomach pains, indigestion or wind

Headaches

Feeling dizzy

Feeling itchý in the genital or vaginal area

Tell your doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

Blood tests

Suprax Tablets can cause blood clots or small changes to the way the liver and kidney work. This would be shown up in blood tests. This is not common and goes back to normal after stopping this medicine

If you think you are reacting badly to the medicine or having any problems, then discuss it with your doctor or phármacist.

5. How to store Suprax

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on label and blister pack

Store below 25° C

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 Suprax 200mg Tablets contain

 Each tablet contains 200mg of the active substance, cefixime.

• The other ingredients are microcrystalline cellulose, pregelatinised starch, calcium hydrogen phosphate dihydrate, magnesium stearate, hypromellose, macrogol 6000 and titanium dioxide (E171).

What Suprax looks like and content of the pack Suprax is available as an off-white, convex, film coated tablet engraved with 'ORO' on one side. Suprax is available in blister packs containing 1, 2, 7 or 14 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder Sanoti-aventis, One Onslow Street Guildford, Surrey, GU1 4YS, UK Tel: 01483 505515

Fax: 01483 535432

email: uk-medicalinformation@sanofi-aventis.com

Manufacturer

Famar Lyon, Avenue de General Gaulle, Saint Genis Laval, France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 09/2008

© Sanofi-aventis, 2008