PACKAGE LEAFLET: INFORMATION FOR THE USER

Suprax 200mg Film-coated Tablets

Cefixime

Is this leaflet hard to see or read?

Phone +353 1800 851 119 for help

Read all of this leaflet carefully before taking 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 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Suprax is and what it is used for
- 2. What you need to know before you take Suprax
- 3. How to take Suprax
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- 6. Contents of the pack and other 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 treating infections in the upper respiratory tract and also in the urinary tract.

2. What you need to know before you take Suprax

Do not take this medicine and tell your doctor if:

You are allergic (hypersensitive) to cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine (listed in Section 6). 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Suprax if:

- ▲ You have ever had colitis
- ▲ You have allergic tendencies such as asthma, rash or hives
- ▲ You have kidney problems
- ▲ The person taking this medicine is a child under the age of 12

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

During or after treatment, you must tell your doctor immediately:

• If you have a severe skin reaction such as an eruption of blisters, red, scaly widespread rash with bumps under the skin, or detachment of the skin which quickly spreads over the whole body and is accompanied by fever and puts you at risk (toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome), drug reaction with eosinophilia and systemic symptoms (DRESS), or acute generalized exanthematous pustulosis (AGEP)).

Other medicines and Suprax

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.

However, if your child has a gastrointestinal disorder (diarrhoea, fungal infection) or blisters, stop breastfeeding or taking the medicine and quickly consult your doctor.

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 12 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 12 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—you 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
- You have 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

- You experience yellowing of the skin
- You experience tiredness, pale skin (sometimes with a yellow tinge) and/or a shortness of breath. This may be due to haemolytic anaemia

Frequency not known:

• Severe allergic reaction including blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals, or layers of skin peeling off. Also, flu-like symptoms, aching muscles, red, scaly widespread rash with bumps under the skin, and fever. These may be a sign of serious allergies called 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis', drug rash with white blood cell disorder (eosinophilia) and systemic symptoms (DRESS), or acute generalized exanthematous pustulosis (AGEP).

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 itchy in the genital or vaginal area
- Fever
- · Shortness of breath

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 changes to the way the liver and kidney work (kidney failure is rare). This would be shown up in blood tests. This is not common and goes back to normal after stopping this medicine.

Suprax Tablets can cause eosinophilia, a blood cell disorder caused by a raised level of one type of blood cell called eosinophils (involved in allergy).

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

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. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie;. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store Suprax

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

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

Do not store above 25°C. Store in the original pack.

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

6. Contents of the pack and other information

What Suprax 200mg Tablets contain

- Each tablet contains 200mg of the active substance, cefixime as cefixime trihydrate.
- 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 Amdipharm Limited,

Temple Chambers, 3 Burlington Road, Dublin 4, Ireland Tel: +353 1800 851 119

email: medical information@advanzpharma.com

Manufacturer
Famar Lyon,
Avenue de General Gaulle,
Saint Genis Laval,
France
Or
S.C. Zentiva S.A.
50 Theodor Pallady Blvd

50 Theodor Pallady Blvd., District 3, 032266 Bucharest ROMANIA

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.

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