

# Size: 100x200mm

## Patient Information Leaflet

### SCOFIX-200 (Cefixime Tablets USP 200mg)

#### Read all of this leaflet carefully before you start using this medicine:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or 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 pharmacist.

#### In this leaflet:

- a) What Scofix-200 is and what it is used for
- b) Before you take Scofix-200
- c) How to take Scofix-200
- d) Possible side effects
- e) How to store Scofix-200
- f) Further information

#### a) WHAT SCOFIX-200 IS AND WHAT IT IS USED FOR

Scofix-200 contains a medicine called cefixime. This belongs to a group of antibiotics called 'cephalosporins'. Scofix-200 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)

#### b) BEFORE YOU TAKE SCOFIX-200

##### Do not take Scofix-200 if:

- You are allergic to cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine.
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.

#### Warnings and precautions:

Talk to your doctor or pharmacist before taking Scofix-200.

- If you have ever had colitis.
- If you have kidney problems.

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

Severe skin problems such as Toxic Epidermal Necrolysis (TEN), Stevens-Johnson Syndrome (SJS), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and Acute Generalised Exanthematous Pustulosis (AGEP) have been reported with cefixime. If you develop severe skin reactions or any of the reactions listed in section 4, stop treatment immediately and contact your doctor or healthcare professional.

#### Other medicines and Scofix-200:

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Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Scofix-200 can affect the way some other medicines work. Also, some medicines can affect the way Scofix-200 works. In particular, tell your doctor if you are taking the following:

- Medicines to thin the blood such as warfarin

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

**Driving and using machines:** This medicine can cause symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. If you experience any of these effects don't drive or use machinery.

**Medical 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 Scofix-200.

#### c) HOW TO TAKE SCOFIX-200

Always take this medicine exactly as your doctor or pharmacist has told you. 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. The recommended 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:** Scofix-200 should not be given to children under 10 years old.

#### If you take more Scofix-200 than you should

If you have too much of this medicine, talk to your doctor straight away.

#### If you forget to take Scofix-200

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 Scofix-200

Do not stop taking this medicine without talking to your doctor. You should not stop taking Scofix-200 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 medicine, ask your doctor or pharmacist.

#### d) POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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

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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,
- SJS/TEN symptoms may include blistering, peeling or bleeding on any part of the skin (including the lips, eyes, mouth, nose, genitals, hands or feet). Also, flu-like symptoms such as fever, chills or aching muscles.
- DRESS symptoms may include flu-like symptoms and a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- AGEP symptoms may include a red, scaly, widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever.
- Erythema multiforme symptoms include 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.
- 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.
- If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath. This may be due to haemolytic anaemia.
- Changes in the way the kidneys are working or blood in your child's urine.
- Fits (convulsions)
- A brain condition with symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. This may be something called encephalopathy. This side effect is more likely if you have taken an overdose or you already have a problem with your kidneys.

#### 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.

**Blood tests:** Scofix-200 can cause blood clots or small changes to the

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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.

#### e) HOW TO STORE SCOFIX-200

Store protected from light at a temperature not exceeding 30°C.

#### F) FURTHER INFORMATION

##### What Scofix-200 contains

The active substance is: Cefixime Trihydrate USP.

Other Ingredients are: Microcrystalline cellulose PH-102 USP, Maize starch USP, Colloidal Anhydrous Silica USP, Magnesium Stearate USP, Purified Talc USP, Croscarmellose Sodium USP, Tulsion 339 (Polacrillin Potassium USP), Sodium Starch Glycolate (Type A) USP, Hypromellose USP, Polyethylene Glycol-6000 USP, Titanium Dioxide USP, Dichloromethane USP & Isopropyl Alcohol USP .

##### What Scofix-200 look like

Off white, elongated, biconvex film coated tablet having breakline on one side and plain on other side.

##### Packing Size: 10x1x10 Alu/Alu Blister.

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