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### Patient Information Leaflet Scofix Suspension (Cefixime for Oral Suspension USP 50 mg/5ml) Cefixime USP as Trihydrate

#### 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 Cefixime for Oral Suspension USP 50 mg/5ml is and what it is used for
- b) Before you take Cefixime for Oral Suspension USP 50 mg/5ml
- c) How to take Cefixime for Oral Suspension USP 50 mg/5ml
- d) Possible side effects
- e) How to store Cefixime for Oral Suspension USP 50 mg/5ml
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#### a) WHAT CEFIXIME FOR ORAL SUSPENSION USP 50 MG/5ML IS AND WHAT IT IS USED FOR

Cefixime for Oral Suspension USP 50 mg/5ml is belongs to a group of medicines called Cephalosporins, which are used for treating mild to moderate infection caused by susceptible organisms.

Cefixime for Oral Suspension USP 50 mg/5ml can be used to treat:

- Acute infection of the middle ear
- Infection causing sudden worsening of long-standing bronchitis
- Uncomplicated acute infection of the bladder
- Acute throat infection caused by bacteria
- Uncomplicated acute infections in the urinary tract (Uncomplicated acute cystitis)
- Uncomplicated acute gonorrhoea

#### b) BEFORE YOU TAKE CEFIXIME FOR ORAL SUSPENSION USP 50 MG/5ML

##### Do not take Cefixime for Oral Suspension USP 50 mg/5ml:

- if you are allergic to cefixime or any of the other ingredients of this medicine. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you are allergic to any other cephalosporin type of antibiotic.
- if you have ever had a severe allergic reaction to penicillin antibiotic or to any other beta-lactam type of antibiotic.

#### Warnings and precautions:

Talk to your doctor or pharmacist before taking Cefixime for Oral Suspension USP 50 mg/5ml.

Before you take Cefixime for Oral Suspension USP 50 mg/5ml you should tell your doctor if you

- Are allergic to penicillin antibiotics or to any other beta-lactam type

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of antibiotics. Not all people who are allergic to penicillins are also allergic to cephalosporins. However, you take special care if you ever had an allergic reaction to any penicillin. This is because you might also be allergic to this medicine.

In patients who develop severe allergic reaction or anaphylaxis (serous allergic reaction which causes difficulty in breathing or dizziness) after administration of Cefixime for Oral Suspension USP 50 mg/5ml, the medicine should be discontinued and appropriate treatment should be given.

- If you have ever been told that your kidneys do not work very well. Also if you are taking any sort of treatment (like dialysis) for kidney failure. You may take Cefixime for Oral Suspension USP 50 mg/5ml but you may need a lower dose. (Children with kidney problems should not get Cefixime for Oral Suspension USP 50 mg/5ml.
- If you have severe or persistent diarrhoea that may be bloody and that may be associated with stomach pain or cramps; these symptoms may occur during or shortly after treatment and signal are rare, but potentially life threatening adverse reaction. Stop taking Cefixime for Oral Suspension USP 50 mg/5ml and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken. Having a course of Cefixime for Oral Suspension USP 50 mg/5ml can temporarily increase the chance that you can get infections caused by other sort of germs on which Cefixime for Oral Suspension USP 50 mg/5ml does not act. For example, thrush (infection caused by a yeast germ called Candida) may occur.

#### Other medicines and Cefixime for Oral Suspension USP 50 mg/5ml:

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

Tell your doctor if you are taking or have taken the following medicine as it may interact with your Cefixime for Oral Suspension USP 50 mg/5ml.

- anticoagulant (blood thinning) therapy
- Effect on laboratory tests
- If you are to undertake any blood or urine tests, inform your doctor that you are taking Cefixime for Oral Suspension USP 50 mg/5ml, as cefixime can alter the results of some of these tests.
- Cefixime for Oral Suspension USP 50 mg/5ml can alter the results of some urine tests for sugar of the types called as Benedict's, Fehling's or with copper sulphate test. As with other cephalosporins, Cefixime for Oral Suspension USP 50 mg/5ml can alter the results of a blood test for antibodies called direct Coomb's test.

**Pregnancy, breast-feeding and fertility:** This medicine is specially made for children. However, if you are taking this medicine as an adult, you should 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.

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**Driving and using machines:** Cefixime can cause dizziness. If affected, you should not drive or operate machinery.

#### c) HOW TO TAKE CEFIXIME FOR ORAL SUSPENSION USP 50 MG/5ML

Always take this medicine exactly as your doctor or pharmacist tells you. Check with your doctor or pharmacist if you are not sure.

##### Usual dose for adults and adolescents (12 years and older)

The usual adult dosage is 400 mg daily, either as a single dose or in two divided doses. If your doctor has prescribed one dose a day, it should be taken every 24 hours. If your doctor has prescribed two doses a day, each dose should be taken every 12 hours. The medicine should always be taken at the same time each day.

Children older than 6 months and up to 11 years of age

Children are given Cefixime as an oral suspension (liquid to be taken by mouth). The daily dose is worked out according to the weight of the child.

Usually the total amount each day is 8 mg for each kilogram of body weight in a single dose or divided in 2 doses based on weight.

For exact administration of the dosage the pack is supplied with a 5 ml plastic oral syringe marked at each 0.25 ml. As a general guide to usual doses as following below:

Body weight (kg): 10.0, Daily dose of cefixime (mg): 80, Daily dose (ml) using the graduated syringe: 4 ml (once daily) or 2 ml (twice daily);

Body weight (kg): 12.5, Daily dose of cefixime (mg): 100, Daily dose (ml) using the graduated syringe: 5 ml (once daily) or 2.5 ml (twice daily);

Body weight (kg): 15.0, Daily dose of cefixime (mg): 120, Daily dose (ml) using the graduated syringe: 6 ml (once daily) or 3 ml (twice daily);

Body weight (kg): 17.5, Daily dose of cefixime (mg): 140, Daily dose (ml) using the graduated syringe: 7 ml (once daily) or 3.5 ml (twice daily);

Body weight (kg): 20.0, Daily dose of cefixime (mg): 160, Daily dose (ml) using the graduated syringe: 8 ml (once daily) or 4.0 ml (twice daily);

Body weight (kg): 22.5, Daily dose of cefixime (mg): 180, Daily dose (ml) using the graduated syringe: 9 ml (once daily) or 4.5 ml (twice daily);

Body weight (kg): 25.0, Daily dose of cefixime (mg): 200, Daily dose (ml) using the graduated syringe: 10 ml (once daily) or 5.0 ml (twice daily);

Body weight (kg): 27.5, Daily dose of cefixime (mg): 220, Daily dose (ml) using the graduated syringe: 11 ml (once daily) or 5.5 ml (twice daily);

Body weight (kg): 30.0, Daily dose of cefixime (mg): 240, Daily dose (ml) using the graduated syringe: 12 ml (once daily) or 6.0 ml (twice daily);

Body weight (kg): 37.5, Daily dose of cefixime (mg): 300, Daily dose (ml) using the graduated syringe: 15 ml (once daily) or 7.5 ml (twice daily);

Body weight (kg): >37.5 (and patients 12 years and older), Daily dose of cefixime (mg): 400, Daily dose (ml) using the graduated syringe: 20 ml (once daily) or 10 ml (twice daily);

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**Children less than 6 months of age:** Cefixime for Oral Suspension USP 50 mg/5ml is not recommended for use in children less than 6 months of age.

**Elderly:** For elderly patients, the doses are the same as adults provided the kidney function are normal.

**Kidney problems:** If you have severe kidney problems or are undergoing dialysis, your doctor will reduce your dose.

There are insufficient data regarding the use of Cefixime for Oral Suspension USP 50 mg/5ml in children with kidney problems. It is therefore not recommended for use in these patients.

#### If you take more Cefixime for Oral Suspension USP 50 mg/5ml than you should

If you take more of this medicine than you or it should, contact your nearest hospital casualty department or your doctor immediately.

#### If you forget to take Cefixime for Oral Suspension USP 50 mg/5ml

If you forget to take a dose, take one as soon as you remember. However, if the next dose is due in less than 6 hours, skip the missed dose and go back to your regular dosing schedule.

Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Cefixime for Oral Suspension USP 50 mg/5ml

Do not stop treatment early because it is important that you complete the FULL course of this medicine in order to reduce the chance of the infection returning.

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

#### d) POSSIBLE SIDE EFFECTS

Like all medicines, Cefixime for Oral Suspension USP 50 mg/5ml can cause side-effects, although not everybody gets them.

Allergic reactions: All medicines can cause allergic reactions, although severe allergic reactions are rare (may affect up to 1 in 1,000 people). These can include:

- Sudden wheeziness and tightness of chest,
- Swelling of the eyelids, face or lips,
- Severe skin rashes that can blister and may involve the eyes, mouth and throat and genitals

All of these allergic reactions need urgent medical attention. If you think you are having any of these types of reaction, stop taking this medicine and contact your doctor or your nearest hospital accident and emergency department.

The following other side-effects

Common (may affect up to 1 in 10 people): diarrhoea (if you have severe diarrhoea or if you see blood in your stools, you should stop taking this medicine and talk to your doctor immediately because you may have a very rare infection of the large bowel that needs special treatment).

Uncommon (may affect up to 1 in 100 people): headache, nausea, vomiting, stomach pain, rash, changes in blood tests that check how your liver is working.

Rare (may affect up to 1 in 1,000 people): Serious allergic reaction which

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causes swelling of the face or throat (angioneurotic oedema), hypersensitivity reactions (these are skin rashes that are less severe allergic reactions than mentioned above, lumpy rash [hives], itching), dizziness/vertigo, loss of appetite (anorexia), flatulence (wind), itching, fever, abnormal increase in the number of cells (eosinophils) in the blood characteristic of allergic states, inflammation of mucous membranes, Repeated infections caused by bacteria, Repeated infections caused by fungi, Changes in blood tests that check how your kidneys are working.

Very rare (may affect up to 1 in 10,000): Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flulike symptoms and fever (Stevens-Johnson syndrome)

- Severe blistering rash 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 (Toxic epidermal necrolysis)
- Hypersensitivity reaction causing symptoms like rash, joint pain, fever and shock (serum sickness)
- a feeling of restlessness associated with increased activity (psychomotor hyperactivity)
- Serious allergic reaction which causes difficulty in breathing or shock (anaphylactic shock) inflammation of the intestines that sometimes occurs following antibiotic treatment (antibiotic associated colitis)
- Severe reduction in number of white blood cells which makes infections more likely (agranulocytosis)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- Decreases in the numbers of small cells that are needed for clotting of the blood, which increases the risk of bleeding or bruising (thrombocytopenia) (if you are having a blood test for any reason, tell the person who is taking your blood sample that you are taking this medicine as it may affect your result)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- low counts of white blood cells (leucopenia)
- Reversible inflammation of the kidney affecting its structure and function
- Inflammation of the liver (hepatitis)
- Bile disorder (cholestatic jaundice)
- Changes in special blood tests that show how your kidney is working (blood creatinine increased).

Not known (frequency cannot be estimated from the available data):

- Rise in the number of blood platelets (thrombocytosis);
- Fall in the number of a type of white blood cells (neutropenia);
- Dyspepsia;
- 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'.

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- 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.

#### e) HOW TO STORE CEFIXIME FOR ORAL SUSPENSION USP 50 MG/5ML

- Store protected from light at a temperature not exceeding 30°C.
- Use the reconstituted suspension within 7 days.

#### F) FURTHER INFORMATION

##### What Cefixime for Oral Suspension USP 50 mg/5ml contains

The active substance is: Cefixime USP as Trihydrate.

Other Ingredients are: Xanthan Gum BP, Sodium Benzoate BP, Hydrophobic Colloidal Anhydrous Silica BP, Colour Sunset Yellow FCF, Flavour Vanilla, Sugar (Pharma Grade) BP.

##### What Cefixime for Oral Suspension USP 50 mg/5ml look like

White to light yellow granular powder filled in white HDPE bottle. Light yellow to orange colour suspension after reconstitution.

**Packing Size:** 60ml HDPE bottle packed in unit carton along with leaflet.



#### Scott Edil

Manufacturer:

**Scott-Edil Advance Research Laboratories & Education Limited**

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Baddi-173205, Himachal Pradesh, INDIA

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