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créé le par modifié le par	03/02/2014 Thill G 28/03/2014 Thill G	Nom du produit Référence article Dosage Quantité	Cefodox R771650 100 mg cprs				Code sécurité R771650
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**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Cefodox[®] 100mg Film-Coated Tablets

Cefpodoxime (as proxetil)



Is this leaflet hard to see or read?

Phone 01 403 5600 for help

Read all of the leaflet carefully before you start 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 yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Cefodox Tablets are and what they are used for
2. What you need to know before you take Cefodox Tablets
3. How to take Cefodox Tablets
4. Possible side effects
5. How to store Cefodox Tablets
6. Contents of the pack and other information

1. What Cefodox Tablets are and what they are used for

Cefodox Tablets contains a medicine called cefpodoxime proxetil. This belongs to a group of antibiotics called 'cephalosporins'. Cefodox Tablets are used to treat infections caused by bacteria. These include infections of the:

- nose, sinuses (such as sinusitis)
- throat (such as tonsillitis, pharyngitis)
- chest and lungs (such as bronchitis, pneumonia)
- skin (such as an abscess, ulcer, infected wound, inflamed hair follicles, carbuncles, furuncles, infections around the finger nails, a type of skin infection called cellulitis)
- urinary system (such as cystitis, and kidney infections)
- the sexually transmitted infection, gonorrhoea

2. What you need to know before you take Cefodox Tablets

Do not take this medicine and tell your doctor or pharmacist if:

- You are allergic (hypersensitive) to cefpodoxime, any other 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 pharmacist before taking Cefodox Tablets.

Warnings and precautions

Take special care with Cefodox Tablets

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

- Have ever had colitis
- Have kidney problems

If you are not sure if any of the above applies 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

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medicines you buy without a prescription, including herbal medicines. This is because Cefodox Tablets can affect the way some other medicines work. Also some medicines can affect the way Cefodox Tablets works.

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

- antacids (used to treat indigestion)
- medicines for treating ulcers (such as ranitidine or cimetidine)
- water tablets or injections (diuretics) used to increase the flow of your water (urine)
- aminoglycoside antibiotics (used to treat infections)
- probenecid (used with a medicine called cidofovir to stop kidney damage)
- coumarin anti-coagulants such as warfarin (used to thin the blood)
- oestrogens such as in the contraceptive pill

Take antacids and medicines for ulcers 2-3 hours after Cefodox Tablets.

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 Cefodox Tablets.

Pregnancy and breast-feeding

Talk to your doctor before taking Cefodox Tablets if you are pregnant, might become pregnant or think you may be pregnant. Do not breast-feed if you are taking Cefodox Tablets. This is because small amounts may pass into the mother's milk. If you are pregnant or breast-feeding talk to your doctor or pharmacist before taking any medicine.

Driving and using machinery

You may feel dizzy while you are taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Cefodox Tablets

Cefodox Tablets contain:

- **Lactose:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars talk to your doctor before taking this medicine.

3. How to take Cefodox Tablets

Always take Cefodox Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Take this medicine with or straight after food
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

The dose of Cefodox Tablets depends on your needs and the illness being treated. Your doctor will advise you:

Adults

Infections of the nose/throat

- One tablet twice each day

Infection of the sinuses

- Two tablets twice each day

Infections of the chest and lungs

- One or two tablets, twice each day

Infections of the lower urinary system e.g. cystitis

- One tablet twice each day

Gonorrhoea

- Two tablets as a single dose

Infections of the upper urinary system such as kidney infections

- Two tablets twice each day

Skin infections

- Two tablets twice each day

People with kidney problems

Your doctor may need to give you a lower dose

Children

Children should be given Cefodox Paediatric Granules

Your doctor will advise you of the best way to take your medicine. Always follow his advice about when and how to take your medicine and always read the label on the box. Your pharmacist will also be able to help you if you are not sure.

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Blood tests

If you take this medicine for more than 10 days, the doctor or nurse may do a blood test. This is routine and nothing to worry about.

If you take more Cefodox Tablets than you should

If you have too much of this medicine, talk to your doctor straight away. The following effects may happen: confusion, lack of emotion or interest in anything and agitation.

If you forget to take Cefodox Tablets

If a dose is missed, do not worry. Just wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cefodox Tablets

Do not stop taking your medicine without talking to your doctor. You should not stop taking Cefodox Tablets 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, Cefodox Tablets can cause side effects, although not everybody gets them.

Side effects are described by the number of patients expected to experience the reaction, using the following categories: **very common** (more than 1 in 10 patients), **common** (1 in 100 to 1 in 10 patients); **uncommon** (1 in 1,000 to 1 in 100 patients); **rare** (1 in 10,000 to 1 in 1,000 patients), **extremely rare** (Less than 1 in 10,000 patients); **not known** (cannot be estimated from the available data).

Tell your doctor straight away or go to the nearest hospital casualty department if you notice any of the following serious side effects, whose occurrence is rare, or extremely rare – 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.
- 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 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. This may be something called 'Toxic epidermal necrolysis'.
- 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 is more likely if you are taking the tablets for a long time.
- Yellowing of the skin, eyes or mouth and feeling tired. You may also be more pale than normal. This could be because of a serious type of anaemia.

Other common side effects may include diarrhoea.

Stop taking your medicine and contact your doctor without delay if you get severe diarrhoea. This may be a symptom of a very serious side-effect called pseudomembranous colitis.

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

- Feeling sick (nausea) or being sick (vomiting)
- Stomach pains
- Flatulence (passing wind)
- Loss of appetite
- Headaches
- Feeling dizzy
- Ringing in the ears
- Feeling tired or weak
- Itching skin without rash
- Pins and needles
- Numbness or tingling feelings

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Other side-effects, that rarely occur include blood disorders such as:

- haemolytic anaemia
- neutropenia
- agranulocytosis
- thrombocytopenia
- lymphocytosis
- anaemia
- leukopenia
- leucocytosis
- Symptoms may include jaundice, feeling tired, sudden fever, frequent infections such as sore throat, mouth ulcers.

Your doctor may want to monitor your blood count for changes in blood picture.

Blood tests: Cefodox Tablets can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly. Cefodox Tablets may cause changes in kidney function. If you notice any changes, please contact your doctor.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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IRL - Dublin 2.

Tel: +353 1 6764971,

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Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

5. How to store Cefodox Tablets

Keep out of the reach and sight of children. Do not use Cefodox Tablets after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cefodox Tablets contain

- Each film-coated contains the active ingredient cefpodoxime proxetil equivalent to 100mg cefpodoxime.
- Other ingredients include magnesium stearate, carmellose calcium, hydroxypropylcellulose, sodium laurilsulfate, lactose monohydrate, titanium dioxide, talc and hypromellose.

What Cefodox Tablets looks like and content of the pack

Cefodox Tablets are curved, cylindrical shaped, white tablets with "208" and beneath "A" engraved on one side. Cefodox is available in cartons of 2, 10 and 20 tablets. Not all pack sizes may be marketed.



Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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60205 Compiègne - 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 April 2014.

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