



PACKAGE LEAFLET

SEFTECH 200 mg Film Coated Tablets

Taken by mouth.

Active substance: Each film-coated tablet contains 260.88 mg cefpodoxime proxetil equivalent to 200 mg cefpodoxime.

Excipients: Carboxymethylcellulose calcium, cross-linked carboxymethylcellulose sodium, sodium lauryl sulphate, hydroxypropylcellulose, lactose monohydrate (from cow's milk), magnesium stearate, Opadry White Y-1-7000 (hypromellose, titanium dioxide, polyethylene glycol).

Read all of this PACKAGE 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 pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

- 1. What SEFTECH is and what it is used for***
- 2. What you need to know before you take SEFTECH***
- 3. How to take SEFTECH***
- 4. Possible side effects***
- 5. How to store SEFTECH***

1. WHAT SEFTECH IS AND WHAT IT IS USED FOR

SEFTECH contains the active substance cefpodoxime proxetil, which belongs to a group of antibiotics called cephalosporins and works by killing bacteria that cause infections.

SEFTECH is presented as film-coated tablets and is taken by mouth. SEFTECH is supplied in blisters containing either 15 or 20 tablets in each package.

For use in children, SEFTECH is also available as dry powder for oral suspension.

SEFTECH is used for the treatment of the following infections caused by susceptible microorganisms:

- Upper respiratory tract infections
 - Tonsillitis, pharyngitis (inflammation of the tonsils and pharynx)
 - Acute sinusitis (inflammation of cavities within the head called sinuses)
 - Acute otitis media (middle ear inflammation in children only)
- Lower respiratory tract infections
 - Acute bronchitis
 - Pneumonia (lung inflammation)
 - Exacerbation of chronic obstructive pulmonary disease (COPD)



- Uncomplicated infections of the lower and upper urinary tract
- Uncomplicated gonococcal urethritis (sexually transmitted gonorrhea infections)
- Skin and soft tissue infections

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SEFTECH

DO NOT USE SEFTECH

- If you are allergic (hypersensitive) to cefpodoxime, other cephalosporins, or any of the other ingredients (see list of excipients) of SEFTECH.
- If you have had an allergic reaction to particular antibiotics (penicillins, monobactams and carbapenems) as you may also be allergic to SEFTECH.

If any of the above applies to your situation, talk to your doctor before using SEFTECH. You should not be given SEFTECH.

TAKE SPECIAL CARE with SEFTECH

- If you have ever been told that your kidneys do not work properly and if you are having any sort of treatment (like dialysis) for kidney failure. You may take SEFTECH but you may need a lower dose.
- If you have ever had an inflammation of your intestines called colitis or any other severe disease affecting your stomach and intestines.
- SEFTECH can alter the results of some blood tests (such as cross-matching blood and the Coombs' test). It is important to tell the doctor that you are taking this medicine if you are going to have any of these tests.
- This medicine can also alter the results of urine tests for sugar (such as Benedict's or Fehling's tests). If you have diabetes and routinely test your urine, tell your doctor. This is because other tests may have to be used to monitor your diabetes while you are having this medicine.

Please consult your doctor even if these warnings were applicable to you at any time in the past.

SEFTECH with food and drink

Take SEFTECH with meals in order to increase its absorption from the intestines.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

The doctor will assess the benefits of SEFTECH treatment for you and the possible risks to your baby. The safety of cefpodoxime proxetil in pregnant women has not been completely established. Therefore, SEFTECH is not recommended during pregnancy.

If you realize that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

SEFTECH can pass to your baby through breast milk. SEFTECH can be used during breastfeeding, but if your baby has diarrhea or fungal infections of the mucosa, you should stop breast-feeding and tell your doctor.

The doctor will assess the benefits of SEFTECH treatment for you and the possible risks to your baby.



Driving and using machinery

SEFTECH may cause dizziness. If you experience such symptoms while taking this medicine, do not drive or use machines.

Important information about some of the other ingredients of SEFTECH

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance (sensitivity) to some sugars, contact your doctor before taking this medicinal product.

Using with other medicines

It is important that you tell your doctor about all the medicines you use, including the ones you buy without a prescription.

SEFTECH may be affected by other medicines that are excreted by the kidneys. This is especially true for the medications that affect the proper functioning of the kidneys. Many medications are available that can cause this condition. Therefore, consult your doctor or pharmacist before using SEFTECH.

Be careful especially when using the following medicines together with this medicine and consult your doctor:

- Antacids (used to treat indigestion and gastrointestinal wounds)
- Medicines such as ranitidine or cimetidine used to treat ulcers
- Tablets or injections used to increase urine flow (diuretics)
- Aminoglycoside antibiotics (used to treat infections)
- Probenecid (used in the treatment of gout)
- Coumarin anti-coagulants such as warfarin (used as blood thinners)
- Estrogens taken as contraceptive

Antacids and medicines used in the treatment of ulcers (such as ranitidine and cimetidine) should be taken 2-3 hours after taking SEFTECH tablets. Your doctor will adjust your treatment accordingly, if necessary.

If you require any tests (blood, urine or diagnostic tests), whilst taking SEFTECH, please ensure that your doctor knows that you are taking SEFTECH.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE SEFTECH

Instructions for proper use and dose/administration frequency

The usual recommended dose and frequency of doses for adults are as follows:

Upper respiratory tract infections:

- Inflammation of the tonsils (Tonsillitis): The daily dose is 200 mg taken as 100 mg film coated tablet every 12 hours.
- Inflammation of the pharynx (Pharyngitis): The daily dose is 200 mg taken as 100 mg film coated tablet every 12 hours.
- Acute sinusitis: The daily dose is 400 mg (2 film coated tablets) taken as 1 film-coated tablet every 12 hours.



Lower respiratory tract infections:

- Acute bronchitis: The daily dose is 200 mg taken as 100 mg film coated tablet every 12 hours. Depending on the severity of the infection, the dose can be increased to 200 mg film coated tablet every 12 hours, if required.
- Bacterial pneumonia (lung inflammation): The daily dose is 400 mg (2 film coated tablets) taken as 1 film coated tablet every 12 hours.
- Exacerbations of chronic obstructive pulmonary disease (COPD): The daily dose is 400 mg (2 film coated tablets) taken as 1 film coated tablet every 12 hours.

Urinary tract infections:

- Uncomplicated lower urinary tract infection:
The daily dose is 200 mg taken as 100 mg film coated tablet every 12 hours.
- Uncomplicated upper urinary tract infection:
The daily dose is 400 mg (2 film coated tablets) taken as 1 film coated tablet every 12 hours.
- Uncomplicated gonococcal urethritis:
The daily dose is 200 mg (1 film coated tablet) taken as a single dose.

Skin and soft tissue infections:

The daily dose is 400 mg (2 film coated tablets) taken as 1 film coated-tablet every 12 hours.

Route and method of administration

- SEFTECH is taken by mouth.
- Swallow your tablet whole with a glass of water.
- It is important that you take your medicine at the scheduled times of the day.
- Take your tablets with meals for optimum absorption.

Different age groups

Use in children

SEFTECH Powder for Oral Suspension form is used in children. The recommended average dose is 8 mg/kg/day divided into 2 doses. The tablet form should be used at doses above 200 mg/day.

Use in the elderly

There is no need for dose adjustment in the elderly, unless there is a problem of kidney failure.

Use in special conditions

Kidney failure

If you have kidney failure, the dose of your medicine should be reduced. See your doctor for this. SEFTECH is excreted from the body through the kidneys. It should be used with caution in cases of severe kidney failure. In this case, your doctor may reduce the dose or interrupt the treatment.

Liver failure

No dose adjustment is required in cases of liver failure.

If you have an impression that the effect of SEFTECH is too strong or too weak, talk to a doctor or pharmacist.

If you take more SEFTECH than you should

If you have taken more SEFTECH than you should, talk to a doctor or pharmacist.



If you forget to take SEFTECH

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then continue your treatment as scheduled.

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

Effects that may occur when treatment with SEFTECH is stopped

Do not stop taking SEFTECH without talking to your doctor. If you stop the treatment early, symptoms of infection may come back and your condition may get worse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SEFTECH can cause side effects in patients with hypersensitivity to its ingredients.

If you get any of the followings, stop using SEFTECH and IMMEDIATELY contact your doctor or go to the nearest hospital emergency department:

- Difficulty breathing, and wheezing
- Swelling of the face, tongue or throat which causes difficulty in swallowing or breathing
- Skin redness and rash with widespread itching
- Flu-like symptoms and fever accompanied by blistering and bleeding of the skin around the lips, eyes, mouth, nose and genitals (this may be a condition called ‘Stevens-Johnson syndrome’)
- Formation of fluid-filled blisters on the skin and peeling of large areas of the skin accompanied by fever, chills, muscle pain and general state of malaise (this condition is called ‘toxic epidermal necrolysis’)
- Skin rash with a pink/red ring and a pale center which is itchy and filled with fluid, especially on the palms and soles (this condition is called ‘erythema multiforme’)

These are all very serious side effects.

If you have any of these, it means that you are severely allergic to SEFTECH. You may need urgent medical attention or hospitalization.

All of these very serious side effects occur very rarely.

Tell your doctor straight away or go to the nearest hospital emergency department if you have any of the following side effects:

- Severe and persistent or bloody diarrhea
- Yellowing of the skin and eyes accompanied by extreme fatigue (jaundice)
- Extreme fatigue and more frequent infections, especially in long-term use.

These are all serious side effects. You may need urgent medical attention.

All of these serious side effects occur very rarely.

Tell your doctor if you notice any of the following side effects:

Common (affecting less than 1 in 10 patients)

- Abdominal bloating
- Nausea
- Vomiting
- Abdominal pain
- Flatulence
- Diarrhea
- Loss of appetite



Uncommon (affecting less than 1 in 100 patients)

- Hypersensitivity reactions (rash, urticaria and pruritus that are less severe allergic reactions than mentioned above)
- Headache
- Numbness and tingling
- Dizziness
- Ringing in the ears
- Tiredness and feeling unwell

Rare (affecting less than 1 in 1,000 patients)

- Changes in blood tests that check how your liver is working
- Anemia
- Decrease in the number of blood cells (symptoms include weakness, newly emerging infections and easy bruising or bleeding)
- Increase in the number of some types of white blood cells
- Increase in the number of cells necessary for blood clotting.

Very rare (affecting less than 1 in 10,000 patients)

- Anaphylactic reactions (e.g. bronchospasms, purpura and edema of the face, hands and feet)
- Worsening kidney function
- Liver damage
- Receiving SEFTECH treatment can temporarily increase the risk of getting infections caused by other types of germs. For example, thrush may occur.
- A type of anemia that can be severe and is caused by the destruction of red blood cells.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SEFTECH

Keep SEFTECH out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

Use it in accordance with the expiry date.

Do not use SEFTECH after the expiry date, which is stated on the package.

If you notice a defect in the product and/or its packaging, do not use SEFTECH.

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.

Marketing Authorization Holder:

DEVA Holding A.Ş.

Küçükçekmece - İSTANBUL/TÜRKİYE



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Module 1.3.1 Package Leaflet



Manufacturing Site:

DEVA Holding A.Ş.

Kapaklı - TEKİRDAĞ/TÜRKİYE

This package leaflet was approved on 11/12/2018.