PATIENT INFORMATION LEAFLET

CEFDIFIX 250 mg/5 ml Powder for Oral Suspension

For oral use.

- ***Active substance:*** Each 5 ml suspension contains 250 mg cefdinir.
- ***Excipients:*** Sucrose, xanthan gum, sodium benzoate, trisodium citrate dihydrate, citric acid (anhydrous), magnesium stearate, colloidal silicon (anhydrous), strawberry flavor.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using 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 only. Do not pass it on to others.*
- *Please state that you are using this drug if you visit a doctor or hospital during the administration of this drug.*
- *Please follow the instructions here precisely. Do not apply higher or lower dose other than the recommended.*

What is in this leaflet:

There are these titles.

1. What CEFDIFIX is and what is it used for?

CEFDIFIX contains the active ingredient cefdinir, which is used orally and belongs to the antibiotic drug group known as cephalosporin.

CEFDIFIX is available in 125 ml bottles in the form of whitish - light yellow colored powder for oral suspension.

CEFDIFIX is used in the treatment of the following infections (inflammatory microbial disease) caused by bacteria (microbes):

CEFDIFIX is used in the treatment of the following diseases:
Adolescents and adults:
a. Community-acquired pneumonia (pneumonia),
b. In acute exacerbation of chronic bronchitis,
c. Acute bacterial infection of the nose and sinuses,
d. In pharyngitis / tonsillitis,

e. For uncomplicated skin and soft tissue infection.

Children:
a. Acute bacterial infection of the nose and sinuses,
b. In pharyngitis / tonsillitis,
c. For uncomplicated skin and soft tissue infections.

2. What you need to know before you use CEFDIFIX?

Do NOT use CEFDIFIX in following cases.
Do not use CEFDIFIX if you are allergic to cefdinir, other cephalosporins or any of the excipients of the drug.

USE CEFDIFIX CAREFULLY in following cases:
If;
• If pseudomembranous colitis (severe, persistent, bloody diarrhea with abdominal pain and fever) occurs due to the use of cefdinir (if severe diarrhea occurs during or after the use of CEFDIFIX, do not take anti-diarrheal drugs and report the situation to your doctor immediately)
• If you have kidney failure (see special use cases in section 3)
• If you have a known hypersensitivity to penicillins (inform your doctor as you may also be hypersensitive to cephalosporins)

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Using CEFDIFIX with food and drink
CEFDIFIX can be used before or after meals.

Pregnancy
Consult with your doctor or pharmacist before you use this drug.

CEFDIFIX should not be used during pregnancy unless necessary. As with other drugs, use of the drug during pregnancy should only be used in cases where the expected benefit is higher than the risk to the fetus and with the advice of a doctor.

If you notice that you are pregnant during treatment, ask your doctor or pharmacist.

Breastfeeding
Consult with your doctor or pharmacist before you use this drug.
CEFDIFIX should not be used during breastfeeding. However, it cannot be excluded that there is a risk for the child who is breastfed. It should be applied by your doctor by evaluating the benefit-harm ratio.

Driving and operating machinery
CEFDIFIX should not effect your ability to drive or operate machine.

Important information about some excipients in the content of CEFDIFIX.
Each 5 ml dose of CEFDIFIX contains 1980,750 mg of sucrose. Therefore, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Using with other drugs

- Do not take antacids (medicines for heartburn and stomach pain) containing aluminum or magnesium at the same time as CEFDIFIX. If you need to use these drugs, take CEFDIFIX at least 2 hours before or 2 hours after taking these drugs.
- Probenecid, which is also used in the treatment of gout (drop disease), causes an increase in its concentration in the blood by prolonging the excretion time of CEFDIFIX from the kidneys. Inform your doctor if you are using this medicine.
- Medicines and foods containing iron reduce the absorption of CEFDIFIX. If iron-containing drugs are to be used during CEFDIFIX treatment, there should be at least 2 hours between the two applications. Especially when used with drugs or foods containing iron, stool color may be red (This color change is considered normal).
- The use of CEFDIFIX may affect the results of some laboratory tests (direct Coombs test; test to investigate the presence of anemia).

Tell your doctor or pharmacist if you are taking or recently have taken any other medicines that you buy with or without a prescription.

3. How to use CEFDIFIX?

Always strictly follow your doctor's instructions while using CEFDIFIX. If you are unsure, ask your doctor or pharmacist.

Instructions for proper use and dosage/administration frequency:

Infants and children from 6 months to 12 years:

a. In acute otitis media; A total daily dose of 14 mg/kg/day with two doses (in two doses, 7 mg/kg per dose) or as a single dose (14 mg/kg) for 10 days, 5-10 days in cases older than 2 years of age,
b. In tonsillitis/pharyngitis (caused by group A streptococcus); a total daily dose of 14 mg/kg/day with two doses (in two doses, 7 mg/kg per dose) for 5-10 days or as a single dose (14 mg/kg) for 10 days,
c. In uncomplicated skin and soft tissue infections; It is used for 10 days with two doses (in two doses, 7 mg/kg per dose) with a total daily dose of 14 mg/kg/day.

Adolescents and adults:

a. In community-acquired pneumonia; 10 days with two doses (300 mg per dose, in two doses) with a total daily dose of 600 mg,
b. In acute exacerbation of chronic bronchial infection; In two doses (in two doses, 300 mg per dose) with a total daily dose of 600 mg or as a single dose (600 mg) for 5-10 days.
c. In acute infection of the nose and sinuses; A total daily dose of 600 mg in two doses (in two doses, 300 mg per dose) or as a single dose (600 mg) for at least 7-14 days
d. In tonsillitis/pharyngitis (caused by group A streptococcus); A total daily dose of 600 mg in two doses (in two doses, 300 mg per dose) for 5-10 days or as a single dose (600 mg) for 10 days,
e. In uncomplicated skin and soft tissue infections; 10 days with two doses (in two doses, 300 mg per dose) with a total daily dose of 600 mg/day,

It is recommended to use dosage and pharmaceutical dosage forms suitable for adults. Oral suspension and sachet forms can be used in patients with swallowing difficulties.

Method of administration:

CEFDIFIX is only taken orally.

Preparation of the suspension:
Before preparing the suspension, the powder is loosened/aerated by inverting and shaking with the bottle closed. Boiled, cooled water is poured up to half of the marking line on the bottle and shaken well. It should be waited for 5 minutes for a homogeneous (all with similar characteristics) distribution. After this process, water is added again up to the marking line on the bottle and shaken. The reconstituted suspension can be stored in the refrigerator at 2°-8°C for 10 days. The bottle should be shaken well before each use.

The measuring spoon supplied with the bottle should be used to take the dose accurately.

Different age groups

Administration in Children:
Its efficacy and safety in children under 6 months have not been established. Cefdinir should not be given to babies younger than 6 months old.

Administration in elderly:
Dose adjustment is not required in elderly patients without renal disease.

Special use cases:
Kidney failure:
If you have kidney failure or hemodialysis, your doctor will make the dose adjustment according to kidney function values.

Liver failure:
There is no need for dose adjustment in liver failure.

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

If you use more CEFDIFIX than you should:
If you have taken more CEFDIFIX than you should, consult a doctor or pharmacist.
Take your medicine with you when you go to the doctor or hospital.
There are insufficient data on overuse of cefdinir in humans. With the overuse of other β-lactam antibiotics, symptoms of intoxication such as vomiting, nausea, gastric pit discomfort, diarrhea and confusion are observed. Since blood dialysis removes cefdinir from the body immediately in individuals with kidney disease; It helps prevent serious poisoning events.

If you forget to use CEFDIFIX:
If you forgot to use a dose of CEFDIFIX, take the dose when you remember and take the next dose on time.
Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with CEFDIFIX is terminated
Even if you feel well, do not suddenly stop using the drug without consulting your doctor. Terminating the treatment without the advice of your doctor may cause aggravation of your disease and delay in the treatment.

If you encounter any problems with the use of CEFDIFIX, consult your doctor or pharmacist.

You can stop using CEFDIFIX by consulting your doctor.

4. Possible side effects

Like all medicines, patients with sensitivity to the ingredients of CEFDIFIX may experience side effects although not everybody gets them.

If any of the following effects occur, stop using CEFDIFIX, and inform your doctor immediately or contact your nearest hospital emergency department.

- Swelling of the hands, feet, wrists, face, lips, or swelling of the mouth or throat making it difficult to swallow or breathe (these may indicate that you have a serious allergy to the drug)
- Diarrhea, which can be severe, persistent, bloody, with abdominal pain and fever (this may indicate pseudomembranous colitis, a rare serious intestinal inflammation due to prolonged antibiotic use.)
- Intestinal knotting (ileus), upper digestive tract (upper gastrointestinal tract) bleeding
- Heart failure, heart attack (myocardial infarction), chest pain
- Asthma exacerbation, respiratory failure
- A type of lung inflammation (idiopathic interstitial pneumonia)
- Liver inflammation (hepatitis), liver failure
- Serious skin diseases (toxic epidermal necrosis)
- Acute kidney failure
- Disease with fever, pinpoint redness and bruising on the skin, confusion, headache and a decrease in the number of platelets (idiopathic thrombocytopenic purpura)

These are all very serious side effects. If you have one of these, you have a serious allergy to CEFDIFIX.
You may need urgent medical attention or hospitalization.
All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor immediately or go to the nearest hospital emergency department:

- Some skin diseases with rash and itching (exfoliative dermatitis, erythema multiforme, erythema nodosum)
- Loss of consciousness
- High blood pressure (hypertension)
- Wound in the stomach and/or duodenum (peptic ulcer)
- Increase or decrease in the number of white blood cells
- Increase in blood eosinophil counts (a type of allergy cell)
- Increase or decrease in blood platelet (coagulating blood cell, platelet) counts (may manifest as unusual bleeding tendencies)
- A type of anemia (hemolytic anemia)
- Low level of colored substance (hemoglobin) that carries oxygen to the tissues in erythrocytes (red blood cells).
- Changes in electrolyte (such as calcium, phosphorus, potassium) levels
- Striated muscle tissue destruction (rhabdomyolysis)
- Kidney disease (nephropathy)

All these are serious side effects. Emergency medical attention may be required.
Serious side effects are very rare.

Tell your doctor if you notice any of the following:

- Vaginal inflammation (vaginitis)
- Vaginal thrush (vaginal moniliasis)
- Stool changes (such as diarrhea or constipation)
- Indigestion (dyspepsia)
- Flatulence
- Nausea
- Stomach ache
- Dry mouth
- Rash
- Itching
- Headache
- Feeling dizzy
- Temporary elevations in blood tests showing bone and liver function
- Changes in blood tests showing kidney function
- Blood coagulation disorders
- Involuntary movements
- Elevation of white blood cells and protein in the urine
- Increase or decrease in urine density

These are the mild side effects of CEFDIFIX.

Reporting of side effects
If you get any side effects, stated or not stated in the Patient Information Leaflet, talk to your doctor or pharmacist. Also, please report the side effects you have to Turkish Pharmacovigilance Center (TÜFAM) by either clicking to "Reporting Drug Side Effect" icon on www.titck.gov.tr or calling side effect reporting line via 0 800 314 00 08. By reporting the side effects you can help provide more information on the safety of this medicine.

TÜFAM	Turkish Pharmacovigilance Center www.titck.gov.tr

5. How to store *CEFDIFIX*?

Keep CEFDIFIX in its package and out of sight and reach of children.

Store at room temperature below 25 °C and its box.
After reconstitution, it can be stored in the refrigerator for a maximum of 10 days.

Use in accordance with expiration dates.
Do not use CEFDIFIX after the expiry date on the package.
If you notice any defects in the product and / or packaging, do not use CEFDIFIX.

"Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization. "

Marketing Authorisation Holder:
Humanis Saglik A.S,
Mahmutbey Mah. Tasocagi Yolu Cad. Solen Rezidans Apt. No:19/1/11
Bagcilar-Istanbul-TURKEY

Manufacturer:
PharmaVision San. ve Tic. A.S.
Topkapı/Zeytinburnu/İstanbul/Türkiye

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