Package Leaflet: Information for the user

Cefixime Nectar Lifesciences 100mg/5ml Powder for Oral Suspension cefixime

Read all of this 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cefixime Nectar Lifesciences Lifesciences is and what it is used for

Cefixime Nectar Lifesciences Lifesciences Powder for Oral Suspension (called "Cefixime Nectar Lifesciences Lifesciences" in this leaflet) belongs to a group of medicines called Cephalosporins, which are used for treating mild to moderate infection caused by susceptible organisms.

Cefixime Nectar Lifesciences Lifesciences 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

2. What you need to know before you take Cefixime Nectar

Lifesciences Lifesciences Do not take Cefixime Nectar

Lifesciences Lifesciences if you
- Are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- Are allergic to any other cephalosporin type of antibiotic.
- 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 Nectar Lifesciences Lifesciences. Before you take Cefixime Nectar Lifesciences Lifesciences you should tell your doctor if you:

- Are allergic to penicillin antibiotics or to any other beta-lactam type 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 Nectar Lifesciences Lifesciences, the medicine should be discontinued and appropriate treatment should be given.

- 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 Nectar Lifesciences Lifesciences but you may need a lower dose. (Children with kidney problems should not get Cefixime Nectar Lifesciences Lifesciences)
- 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 Nectar Lifesciences Lifesciences and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken.

Having a course of Cefixime Nectar Lifesciences Lifesciences can temporarily increase the chance that you can get infections caused by other sort of germs on which Cefixime Nectar Lifesciences Lifesciences does not act. For example, thrush (infection caused by a yeast germ called Candida) may occur.

Other medicines and Cefixime Nectar Lifesciences Lifesciences
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 Nectar Lifesciences Lifesciences:

- 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 Nectar Lifesciences Lifesciences, as cefixime can alter the results of some of these tests.
    - Cefixim Nectar Lifesciences Lifesciences 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 Nectar Lifesciences Lifesciences 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.

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

Cefixime Nectar Lifesciences Lifesciences with food and drink
Cefixime Nectar Lifesciences Lifesciences may be taken with or without food.

Important information about some of the ingredients of Cefixime
Cefixime Nectar Lifesciences Lifesciences contains:

- **Sucrose:** This medicine contains approximately 2.33 g of Sucrose in each 5 ml after reconstitution. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth when the medicinal product may be intended for chronic use, e.g. for two weeks or more.
- **Sodium Benzoate:** This medicine contains 10.0 mg of sodium benzoate in each 5 ml after reconstitution. Sodium Benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Cefixime Nectar Lifesciences

Always take this medicine exactly as your doctor or pharmacist has told 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 see following table.

Body weight (kg)	Daily dose of cefixime (mg)	Daily dose (ml) using the graduated syringe (dose can be given as a single dose or divided in 2 doses)
10.0	80	4 ml (once daily) or 2 ml (twice daily)
12.5	100	5 ml (once daily) or 2.5 ml (twice daily)
15.0	120	6 ml (once daily) or 3ml (twice daily)
17.5	140	7 ml (once daily) or 3.5 (twice daily)
20.0	160	8 ml (once daily) or 4 ml (twice daily)
22.5	180	9 ml (once daily) or 4.5 ml (twice daily)
25.0	200	10 ml (once daily) or 5 ml (twice daily)
27.5	220	11 ml (once daily) or 5.5 ml (twice daily)
30.0	240	12 ml (once daily) or 6 ml (twice daily)

37.5	300	15 ml (once daily) or 7.5 ml (twice daily)
> 37.5 (and patients 12 years and older)	400	20 ml (once daily) or 10 ml (twice daily)

Children less than 6 months of age
Cefixime Nectar Lifesciences 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 Nectar Lifesciences in children with kidney problems. Cefixime Nectar Lifesciences is therefore not recommended for use in these patients.

How to prepare Cefixime Nectar Lifesciences
For 50 ml: Shake to loosen the powder. Add 35 ml of water in two portions to the dry mixture in the bottle. Shake well after each addition. Further dilution is not recommended.
For 100 ml: Shake to loosen the powder. Add 69 ml of water in two portions to the dry mixture in the bottle. Shake well after each addition. Further dilution is not recommended.

If you take more Cefixime Nectar Lifesciences 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 Nectar Lifesciences
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 Nectar Lifesciences
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.

4. Possible side effects

Like all medicines, Cefixime Nectar Lifesciences 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 have been reported:

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 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'.
- 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

Reporting of side effects

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

5. How to store Cefixime Nectar Lifesciences

Keep this medicine out of the sight and reach of children.

Do not use Cefixime Nectar Lifesciences after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of the month.

Unopened: Store below 25ºC. Do not refrigerate or freeze.

After reconstitution, the suspension can be stored below 25°C for 14 days. Do not refrigerate or freeze. Keep bottles tightly closed and shake well before use. Discard any unused portion after 14 days. Dilution of the suspension is not recommended.

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.

6. Contents of the pack and other information

What Cefixime Nectar Lifesciences contains

- The active substance is cefixime.
  The other ingredients are Xanthan gum, Sodium benzoate, Silica colloidal anhydrous, Sucrose, Flavour Strawberry Guarana (contains nature identical flavourings, natural flavours, maize maltodextrin and propylene glycol)

What Cefixime Nectar Lifesciences looks like and contents of the pack

Cefixime Nectar Lifesciences is off white to pale yellow colored granular powder with strawberry guarana flavor.

Each 5 ml of reconstituted suspension contains cefixime trihydrate equivalent to 100 mg of cefixime.

Cefixime Nectar Lifesciences comes in Type III amber coloured glass bottle with white CR Closure with Pilfer Proof containing 25 g or 50 g powder for preparation of 50 ml or 100 ml oral suspension respectively.

Bottles are supplied with a measuring cup that have the marking of "35 ml" and "69 ml"; which can measure 35 ml and 69 ml of water for reconstitution.

Bottles are supplied with single 5 ml plastic oral syringe graduated in 0.25 ml divisions.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder
NECLIFE PT UNIPESSOAL, LDA.
Rua Brito Pais nº8C
1495-028 Algés
Portugal

Manufacturer
PHARMADOX HEALTHCARE LTD.
KW20A Kordin Industrial Park
Paola PLA3000, Malta

This medicinal product is authorised in the Member States of the EEA under the following names
Portugal **:** Cefixime Nectar
Germany **:** Cefixim Nectar
Spain **:** Cefixim Neclife
Croatia **:** Cefiksim Nectar
Hungary **:** Cefixime Nectar

Ireland **:** Cefixime Nectar Lifesciences
Italy **:** Cefixime Nectar

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