

DISTACLOR ORAL SUSPENSION

Cefaclor (125mg/5ml, 187mg/5ml)

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What Distaclor is used for

DISTACLOR contains the active ingredient cefaclor, which is an antibiotic.

Distaclor is indicated for the treatment of the following infections due to susceptible microorganisms:

- Bronchitis (inflammation of the air passages)
- Infection of lung tissue (pneumonia)
- Upper respiratory tract infections
- Middle ear infections (otitis media)
- Skin and soft tissue (e.g. muscle) infections
- Infection of the sinuses (sinusitis)
- Urine tract (Bladder and kidney) infections and Gonococcal urethritis (inflammation of the urethra caused by gonorrheal infection)

How Distaclor works

Distaclor contains active ingredient cefaclor.

Cefaclor is a type of antibiotic called cephalosporin. Cefaclor is used to treat infections with bacteria.

Before you take Distaclor

- **When you must not take it**

Do not take Distaclor if you have an allergy to:

- Any cephalosporin antibiotic, such as cefalexin, cefuroxime, cefradine, Cefaclor or Penicillins.

An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- **Before you start to use it:**

Tell your doctor if you have or have had:

1. Allergies to:
 - any other medicines including cephalosporins, penicillins, other antibiotics or things known to cause allergy.
You may have an increased chance of being allergic to cefaclor if you are allergic to cephalosporins, penicillins or other allergens.
 - any other substances, such as foods, preservatives or dyes.

2. Any medical conditions, especially the following:

- kidney disease
- bowel conditions or diseases such as colitis

Please consult your doctor before you start to use Distaclor if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Distaclor against the benefits they expect it will have for you.

- **Taking other medicines**

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interact with cefaclor. These include:

- probenecid, a medicine used to treat gout or to prolong the action of certain antibiotics
- medicines used to prevent blood clots such as warfarin

How to use Distaclor

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

Distaclor is administered orally.

The product needs to be reconstituted with water before use. For a proper reconstitution invert bottle and tap to loosen powder

Distaclor can be taken either with or without food. You should try to space the doses evenly throughout the day.

- **How much to use**

Take Distaclor as your doctor has prescribed.

Adults: The usual adult dosage is 250mg every eight hours. For more severe infections (such as Pneumonia) or those caused by less susceptible organisms, doses may be doubled.

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and what type of infection you have.

If you are elderly or if you have kidney disease, your doctor may tell you to take a lower dose.

The usual dose for a child will depend on his or her bodyweight and will be calculated by your doctor.

Babies less than one month should not be given this drug

- **When to use it**

Follow the directions on prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take Distaclor exactly as directed by your doctor.

- **How long to use it**

Unless your doctor tells you otherwise, it is important that you finish the prescribed course of this antibiotic medicine, even if you feel better or it seems the infection has cleared up. Stopping the course early increases the chance that the infection will come back and that the bacteria will grow resistant to the antibiotic.

- **If you forget to use it**

If you forgot to take your medicine, just take your normal dose as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

- **If you use too much (overdose)**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, epigastric distress, and diarrhea. The severity of the epigastric distress and the diarrhea are dose related.

While you are taking Distaclor

It is important to tell your doctor or pharmacist what medicines you are already taking, including those bought without a prescription and herbal medicines, before you start treatment with this medicine. Similarly, check with your doctor or pharmacist before taking any new medicines while taking this one, to make sure that the combination is safe.

- **Things you must do**

- Take Distaclor until you finish the prescription, even if you feel better.
- Stop the administration if allergic reaction occurs.
- If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after you have stopped taking this medicine. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking cefaclor.

- **Things you must not do**

- **Do not use** after the expiry date. Please refer to the outer label for the expiration date.
- 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

- **Things to be careful of**

- Be careful while driving or operating machinery until you know how this medicine affects you.

Tell your doctor if you are having blood or urine tests. Distaclor may interface with these tests.

Side effects

Gastro-intestinal (stomach and intestinal): The most frequent side-effect is diarrhoea. It is rarely severe enough to warrant cessation of therapy. Colitis (inflammation of the lining of the colon), including rare instances of pseudomembranous colitis, has been reported. Nausea and vomiting have been reported rarely.

Hypersensitivity: Allergic reactions such as morbilliform eruptions (rash), pruritus (Severe itching) and urticaria (allergic for skin reaction) have been observed. Serum sickness-like reactions, characterized by findings of erythema multiforme (mild, self-limited rashes), rashes, and other skin manifestations accompanied by arthritis/arthralgia (inflammation of joint/ joint pain), with or without fever. Occasionally, solitary symptoms may occur.

Haematological (blood): Eosinophilia (increase white blood cell count), positive Coombs' tests transient lymphocytosis (increase lymphocytes in blood), and leucopenia (decrease white blood cells in blood)

Hepatic (liver) : Transient hepatitis (inflammation of liver) and cholestatic jaundice (yellowish pigmentation of skin) have been reported rarely with slight elevations in liver enzymes.

Renal (kidney): Reversible interstitial nephritis (spaces between the kidney tubules become swollen) has occurred rarely, also slight elevations in blood urea or serum creatinine or abnormal urinalysis.

Central Nervous System: Reversible hyperactivity, agitation, nervousness, insomnia, confusion, hypertonia (damage to the central nervous system), dizziness, hallucinations and somnolence (drowsiness) have been reported rarely. Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced.

If seizures associated with drug therapy occur, the drug should be discontinued.

Miscellaneous: Genital pruritus (severe itching), vaginitis (inflammation of the

vagina) and vaginal moniliasis (fungal infection).

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Distaclor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Distaclor

- **Storage**

To be stored at controlled room temperature below 30°C. After mixing the oral suspension, store in a refrigerator. Keep tightly closed and shake well before using. The mixture may be kept for 14 days.

- **Disposal**

Discard unused portion after 14 days.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- **What it looks like**

Pink free flowing powder with characteristic strawberry odour.

- **Ingredients**

Active ingredient

- Cefaclor

Inactive ingredients

- Sucrose
- Erythrosine aluminium Lake
- Methylcellulose
- Sodium Lauryl Sulphate
- Artificial Strawberry Flavour
- Dimeticone
- Xanthan Gum F
- Starch Pregelatinized

MAL number:

Distaclor 125mg/5ml Oral Suspension :MAL08021479AC

Distaclor 187mg/5ml Oral Suspension : MAL08042452AC

Manufacturer

FACTA FARMACEUTICI S.p.A.
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Product Registration Holder:

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