

Package leaflet: Information for the user
Distaclor 125mg/5ml & 250mg/5ml Granules for Oral Suspension
Cefaclor

The name of your medicine is Distaclor 125mg/5ml & 250mg/5ml Granules for Oral Suspension, which will be referred to as Distaclor suspension throughout this document.

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 signs of illness 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 Distaclor suspension is and what it is used for**
- 2. What you need to know before you take Distaclor suspension**
- 3. How to take Distaclor suspension**
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1 What Distaclor suspension is and what it is used for

Distaclor suspension is made from granules of the active ingredient cefaclor, which is an antibiotic. Your pharmacist will add fresh clean drinking water to the bottle containing the granules, to make up the suspension, before you are given it.

Distaclor suspension is used to treat the following infections caused by bacteria that can be killed by cefaclor:

- Bronchitis
- Infection of lung tissue (pneumonia)
- Bladder (cystitis) and kidney infections
- Throat infections including tonsillitis and pharyngitis
- Middle ear infections (otitis media)
- Skin and soft tissue (e.g. muscle) infections
- Infection of the sinuses (sinusitis).

2 What you need to know before you take Distaclor suspension.

Do not take Distaclor suspension if

- you are allergic (hypersensitive) to cefaclor, any cephalosporin (other similar antibiotics) or any of the other ingredients of Distaclor capsules (these are listed in Section 6 of this leaflet). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and Precautions

Talk to your doctor before taking Distaclor suspension if you

- have had an allergic reaction to penicillins or other drugs in the past
- have a history of gastrointestinal disease, especially inflammation of the colon (colitis)
- have severe kidney problems

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

Other medicines and Distaclor suspension

Please tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines, including medicines obtained without a prescription. This is especially important for the following, as they may interact with your Distaclor suspension:

- warfarin (a blood thinner)
- probenecid (a treatment for gout).

It may still be all right for you to be given Distaclor suspension and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Distaclor suspension should not affect your ability to drive or use machines.

Distaclor suspension contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sucrose may also be harmful to the teeth.

This medicine contains approximately 3g of sucrose per 5ml dose or 6g of sucrose per 10ml dose.

This should be taken into account if you have diabetes mellitus.

Distaclor suspension contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium free'.

3 How to take Distaclor suspension

Always take Distaclor suspension exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

For adults and the elderly the usual dose is 250mg three times daily. For more severe infections the dose may be doubled. The maximum daily dose is 4g.

Patients with a severe kidney disorder or patients receiving dialysis may need a different dose.

Use in children

For children, and babies over the age of one month, the usual total daily dosage is 20mg/kg (body weight). This total daily dose is usually divided into three and given eight hours apart. For throat and middle ear infections the total daily dose can be divided into two and given twelve hours apart. For more severe infections the dose may be doubled. The maximum daily dose is 1g.

If you take more Distaclor suspension than you should

Go to the nearest accident and emergency department or tell your doctor straight away.

If you forget to take Distaclor suspension

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare. **Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, lips or limbs, rash or itching (especially affecting your whole body).**

Serious side effects

The following side effects are serious. You should stop taking this medicine and contact your doctor immediately if you experience them:

- serious peeling or blistering of the skin
- severe diarrhoea, possibly with blood or mucus.

The following side effects have been reported

- diarrhoea
- feeling sick (nausea)
- vomiting
- measles-like rash, (alone)
- itching
- red wheals on the skin (urticaria) (alone)
- rash with wide spread joint pain and / or stiffness, swollen lymph glands, fever and, possibly, cloudy urine
- swollen arms or legs
- breathlessness
- changes in blood counts, which may show up as bruising or a very tired feeling. You will need a blood test to confirm this.
- damage to your liver or kidneys which can only be detected by a blood and / or urine test
- jaundice (yellow skin and eyes)
- weakness
- pins and needles in the hands or feet
- fainting
- abnormally excitable behaviour
- agitation
- nervousness
- sleeplessness
- confusion
- tight muscles
- dizziness
- seeing or hearing things (hallucinations)
- itching of the vagina caused by thrush (candidiasis).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Distaclor suspension

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

Do not use this medicine after the expiry date which is stated on the container and the carton. The expiry date refers to the last day of the month.

Do not store dry granules above 25°C.

Keep containers tightly closed.

After it is made up, the suspension should be stored in a refrigerator (2-8°C) and be used within 14 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Distaclor suspension contains

The active substance is cefaclor 125 or 250 mg/5 ml

The other ingredients are:

pregelatinised starch, dimethicone, xanthan gum (E415), sucrose, methyl cellulose, sodium laurilsulfate (E487), erythrosine (E127) and strawberry flavouring including dextrins (E1400), ethyl citrate and propylene glycol (E1520).

What Distaclor suspension looks like and contents of the pack

The product is filled into plastic bottles with screw caps containing 100ml of strawberry coloured cefaclor suspension.

The granules may also be filled into individual laminated sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Flynn Pharma Ltd
Marine House
Clanwilliam Place
Dublin 2
Ireland

Manufacturer

ACS DOBFAR S.p.a
Via Laurentina
Km 24,730 Pomezia
00071
Rome
Italy.

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