

Package leaflet: Information for the user

Distaclor MR Tablets 375mg

Cefaclor

The name of your medicine is Distaclor MR tablets 375mg, which will be referred to as Distaclor MR tablets 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 MR tablets are and what they are used for**
- 2. What you need to know before you take Distaclor MR tablets**
- 3. How to take Distaclor MR tablets**
- 4. Possible side effects**
- 5. How to store Distaclor MR tablets**
- 6. Contents of the pack and other information**

1 What Distaclor MR tablets are and what they are used for

Distaclor MR tablets are a long acting tablet. They contain the active ingredient cefaclor, which is an antibiotic.

Distaclor MR 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
- Skin and soft tissue (e.g. muscle) infections

2 What you need to know before you take Distaclor MR tablets

Do not take Distaclor MR tablets if:

- you are allergic to cefaclor, any cephalosporin (other similar antibiotics) 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Distaclor MR tablets

- if you have had an allergic reaction to penicillins or other drugs in the past
- if you have diarrhoea while taking antibiotics

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

Other medicines and Distaclor MR tablets

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 of the following, as they may interact with your Distaclor MR tablets:

- warfarin (a blood thinner)
- probenecid (a treatment for gout).
- antacids containing magnesium hydroxide or aluminium hydroxide, for heartburn and indigestion (these can be bought without prescription).

It may still be all right for you to be given Distaclor MR tablets 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 MR tablets should not affect your ability to drive or use machines.

Distaclor MR tablets contain mannitol

Mannitol may have a mild laxative effect.

3 How to take Distaclor MR tablets

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

The tablets should not be cut, crushed or chewed.

Dosage

Adults and the elderly:

For pharyngitis, bronchitis, tonsillitis, lower urinary tract infections, and skin infections, the usual dose is 375mg (one tablet) taken orally twice daily.

For pneumonia, the usual dose is 750mg (two tablets) taken orally twice daily.

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

Use in Children

Distaclor MR tablets are not recommended for children.

If you take more Distaclor MR tablets than you should

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

If you forget to take Distaclor MR tablets

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor. Do not take a double dose to make up for a forgotten dose.

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

4 Possible side effects

Like all medicines, Distaclor MR tablets 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).

Reporting of side effects

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Distaclor MR tablets

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

Store between 15°C and 25°C.

Store in the original container in order to protect from light.

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

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 to protect the environment.

6 Contents of the pack and other information

What Distaclor MR tablets contain

The active substance is cefaclor.

The other ingredients are:

mannitol, methylhydroxypropylcellulose, hydroxypropylcellulose, methacrylic acid copolymer, stearic acid, magnesium stearate, titanium dioxide (E171), polyethylene glycol, propylene glycol, indigo carmine aluminium lake (E132) and talc.

What Distaclor MR tablets look like and contents of the pack

Distaclor MR is a blue, capsule-shaped, film-coated tablet marked GP5.

Distaclor MR is packaged in foil blister packs of 2 or 14.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Flynn Pharma Ltd
Alton House
4 Herbert Street
Dublin 2
Ireland.

Manufacturer

Facta Farmaceutici SpA
Via Laurentina
Km 24,730
Pomezia 00040
Rome
Italy.

This leaflet was last revised in August 2015



FLYNN
PHARMA
LTD

Artwork for:	Flynn Pharma Limited
Product name:	Distaclor MR Tablets 375mg
Size:	
PL/PA no:	
Type:	Leaflet
Artwork dimensions:	160mm x 260mm
Profile supplied:	Assumed
Date of first artwork:	?
Reason for request:	Revision date edit
Version no:	2 DB
Date of revision:	30 July 2015
Colours:	As swatch(es)
Font(s):	9pt and 10pt FF Zwo
Artwork software:	InDesign CS5.5
BAC ref:	S803

