

PACKAGE LEAFLET: INFORMATION FOR THE USER
ERDOTIN 300 mg CAPSULES
Erdosteine

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Erdotin is and what it is used for
2. Before you take Erdotin
3. How to take Erdotin
4. Possible side effects
5. How to store Erdotin
6. Further information

1. WHAT ERDOTIN IS AND WHAT IT IS USED FOR

Erdotin contains erdosteine, a mucolytic agent, which acts on the phlegm (mucus) in the respiratory tract or airways.

Use:

Erdotin is used to treat the symptoms associated with short, severe episodes of worsening of chronic bronchitis. It is also used as an expectorant.

2. BEFORE YOU TAKE ERDOTIN

Do not take Erdotin

- if you are hypersensitive (allergic) to erdosteine or any of the other ingredients of Erdotin;
- if you suffer from severe liver failure;
- if you suffer from severe decreased kidney function;
- if you have a stomach ulcer.

Take special care with Erdotin

- if you suffer from mild liver failure, you should only take one capsule per day.

Taking other medicines

Erdotin does not usually interfere with other medicines.

However, you should always tell your doctor or pharmacist about all medicines you are taking or planning to take, including any obtained without a prescription.

Taking Erdotin with food and drink

Food and drink have no influence.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The use of erdosteine in pregnant or breast-feeding women is not recommended.

- **Effects on the ability to drive or to use machines**

Erdotin has minor or negligible influence on the ability to drive and use machines.

- **Important information about some of the ingredients of Erdotin**

Erdotin does not contain any ingredients which would influence the safe and effective use of the product.

3. HOW TO TAKE ERDOTIN

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

The usual dose is:

Elderly patients and adults above 18 years: one capsule (300 mg erdosteine) twice a day.

For oral use.

The capsule must be swallowed whole with a glass of water.

The maximum duration of therapy is 10 days.

If you take more Erdotin than you should

If you take too many capsules, by mistake, contact your doctor immediately.

If you forget to take Erdotin

Do not take a double dose to make up for a forgotten dose.

If you stop taking Erdotin

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Erdotin can cause side effects, although not everybody gets them.

Uncommon (from 1 in 1000 to 1 in 100): headache; cold and difficulty in breathing; taste alterations, nausea, vomiting and diarrhoea; swelling of the blood vessels below the skin and mucosal tissues due to allergic reaction (angioedema); other skin allergic reactions, such as itching and redness of the skin, oedema and eczema.

Common (from 1 in 100 to 1 in 10): stomach pain (heartburn)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

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 ERDOTIN

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

Do not use Erdotin after the expiry date which is stated on the carton and on the blister after "EXP".

The expiry date refers to the last day of that month.

Do not store above 25°C

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.

6. FURTHER INFORMATION

What Erdotin contains

- The active ingredient is erdosteine.
- The other ingredients are: microcrystalline cellulose, povidone, magnesium stearate.
- The ingredients of the capsule shell are: gelatin, titanium dioxide (E171), iron oxide, yellow (E172), indigotine (E132).

What Erdotin looks like and contents of the pack

Erdotin is a capsule with a green cap and yellow body and is packed in PVC/PVdC/Aluminium blister packs.

Pack sizes: box of 20 and 60 capsules.

Not all these packs may be marketed.

Marketing Authorisation Holder:

Galen Limited

Seagoe Industrial Estate

Craigavon

BT63 5UA

UK

Manufacturer:

Edmond Pharma S.r.l.

Strada Statale dei Giovi 131

20037 Paderno Dugnano MI

Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Erdotin

United Kingdom: Erdotin

Ireland: Erdotin

This leaflet was last revised in June 2019

Erdotin is a trade mark.