PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a physician's prescription only.

ERDOTIN
300 mg
CAPSULES

Each capsule contains:
Erdosteine 300 mg

For the list of inactive ingredients and allergens in the medicine, see: section 6, "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your physician or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is this medicine intended for?

Used as an expectorant in acute and chronic respiratory diseases.

Therapeutic group: Expectorants.

2. Before using the medicine

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient Erdosteine or to any of the additional ingredients that the medicine contains (please see section 6, "Additional information").
- You suffer from stomach or intestinal injury (active peptic ulcer).
- You suffer from renal failure with creatinine clearance lower than 25 ml/min or you suffer from severe liver failure.
- You suffer from hepatic cirrhosis or from a deficiency of the cystathionine-synthetase enzyme.

Special warnings regarding use of the medicine

Before treatment with Erdotin, consult with your physician.

Drug interactions
If you are taking or have recently taken any other medicines, including non-prescription medicines or nutritional supplements, tell your physician or pharmacist.
There are no known harmful interactions with other medicines. **Erdotin** can therefore be used together with antibiotics and bronchodilators (theophylline or beta-2 agonists, cough suppressants, etc.).

Pregnancy, breastfeeding and fertility

Erdotin has not been tested in pregnant or nursing women. If you are pregnant, think you may be pregnant, are planning to become pregnant or breastfeeding, ask your physician for advice before using **Erdotin**.

Driving and using machines
Erdotin has no influence on the ability to drive or use machines.

3. How should you use the medicine?

Always use this medicine according to your physician's instructions. You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen with this medicine.
The dosage and treatment regimen will be determined by your physician only. The usual dosage is generally:
1 capsule 2-3 times a day, for oral use.

Do not exceed the recommended dose.

Do not chew! Swallow the whole capsule with a glass of water.
There is no information about opening and dispersing the capsule.

If you have accidentally taken a higher dose, there may be sweating, hot flashes and dizziness. If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately consult with a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the intended time, do not take a double dose to make up for the forgotten dose. Take the next dose at the regular time and consult your physician.

Adhere to the treatment regimen as recommended by your physician.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult your physician or pharmacist.

4. Side effects

As with any medicine, the use of **Erdotin** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

During use of this medicine rare side effects (effects that occur in 1-10 users out of 10,000) connected to the digestive system may occur.

Nervous system disorders Very rare side effects (effects that occur in fewer than one user in 10,000)	Headache
Respiratory, thoracic and mediastinal disorders Very rare side effects (effects that	Shortness of breath

occur in fewer than one user in 10,000) Side effects whose frequency is not known (effects whose frequency has not yet been determined)	 Bronchial obstruction
Gastrointestinal disorders Very rare side effects (effects that occur in fewer than one user in 10,000)	 Taste alterations, nausea, vomiting, diarrhea, pain in the upper and central abdomen (epigastric pain)
Skin and subcutaneous tissue disorders Very rare side effects (effects that occur in fewer than one user in 10,000)	 Urticaria, erythema, eczema

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How should the medicine be stored?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.

Do not use this medicine after the expiry date (exp.date) which appears on the package. The expiry date refers to the last day of that month. The expiry date refers to the medicine when stored in its original package in accordance with storage conditions.

Store at a temperature below 25°C.

The possible presence of a sulphureous odor in **Erdotin** does not indicate a change in the medicine. Rather, this is a characteristic odor of the active ingredient.

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

6. Additional information

- In addition to the active ingredient Erdosteine, the medicine also contains: Microcrystalline cellulose, Povidone K30, Magnesium stearate, Gelatine, Titanium dioxide (E171), Yellow ferric oxide (E 172), Indigotine (E 132).

- **What the medicine looks like and what the package contains:**

  Erdotin 300 mg: Green-yellow colored gelatin capsules containing ivory colored powder. The capsules are packaged in blister strips. There are 20 capsules in a package.

- **Registration holder and address: MegaPharm Ltd.**, P.O.B. 519, Hod Hasharon 4510501

- **Manufacturer and address: EDMOND PHARMA S.R.L., ITALY**
  VIA DEI GIOVI 131-20037 PADERNO DUGNANO (MI), ITALY

- Revised in June 2021 according to Ministry of Health guidelines

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 135-02-31112