

ERDOMED[®] 300mg

Dispersible Tablets

Erdosteine 300mg Dispersible Tablets

Consumer Medication Information Leaflet (RiMUP)

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1. What Erdomed[®] is used for

Erdomed[®] is used in reducing mucus thickness especially in both acute and severe respiratory disorders associated with excessive mucus production.

2. How Erdomed[®] works

Erdomed[®] contains of *erdosteine*, a mucolytic agent, which acts on the phlegm (mucus) in the respiratory tract or airways.

3. Before you use Erdomed[®]

When you must not use it

Do not use Erdomed[®]:

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

Before you start to use it

Pregnancy and Breast-feeding

Talk to your doctor or pharmacist before using this medicine if you are pregnant, might become pregnant or are breast-feeding. The use of Erdomed[®] in pregnant or breast-feeding women is not recommended.

Driving and using machines

Erdomed[®] has minor or negligible influence on the ability to drive and use machines.

Important information about some of the ingredients of Erdomed[®]

Erdomed[®] does not contain any ingredients which would influence the safe and effective use of the product.

Use in children

Erdomed[®] is not recommended to be used in children younger than 18 years old.

Taking other medicines

Erdomed[®] 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.

4. How to use Erdomed[®] How much and when to use it

Erdomed[®] is intended to be administered orally.

Always use Erdomed[®] exactly as your doctor has told you. You should check with your doctor or pharmacist if you have doubts. The usual dose for elderly patients and adults above 18 years: one tablet (300 mg *erdosteine*) 2-3 times a day.

The tablets should be dissolved in a glass of water. The dispersion should be stirred with a spoon and drunk immediately.

How long to use it

Your doctor will tell you how long your treatment with Erdomed[®] will last.

Do not stop using Erdomed[®] without telling your doctor or

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

If you forget to use it

Do not take a double dose to make up for a forgotten dose. Just continue your next dose.

If you use too much (overdose)

With dosages exceeding those recommended (1200 mg/day) sweating, vertigo and flushing have been observed. If accidentally swallowed / taken an overdose of Erdomed[®] inform your doctor immediately or go to the nearest hospital.

5. While you are using Erdomed[®]

Things you must do

Follow your doctor's instruction when you are taking Erdomed[®]

Things you must not do

Do not use Erdomed[®] after the expiry date which is stated on the carton and blister.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Erdomed[®] to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- if you suffer from mild liver failure, you should only take one tablet per day.
- Erdomed[®] 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

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without a prescription.

- If your doctor has diagnosed an intolerance to some sugars (*i.e.*: *Lactose*) contact your doctor before taking this medicine.
- *Sun-set yellow (E110)* can cause allergic reactions. The presence of sulphureous odour is not sign of product modification, but is a characteristic of the active ingredient.
- the safety of erdosteine in human pregnancy has not been established, therefore, as with all new drugs, its use is not recommended.
- its use is not recommended during breast-feeding.
- If your doctor has diagnosed an intolerance to some sugars contact your doctor before taking this medicine.

6. Side effects

Like all medicines, Erdomed[®] 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 you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines(AEFI)].

7. Storage and disposal of Erdomed[®]:

Keep out of the reach and sight of children. Store below 30°C.

Do not use Erdomed[®] after the expiry date stated on the label after 'Exp'. The expiry date refers to the last day of that month.

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.

8. Product description

What it looks like

Erdomed[®] Dispersible Tablets are packed in Pa/Alu/PVC//Alu blisters. Pack sizes: box of 20 and 30 tablets

Ingredients

The active ingredient is *erdosteine*. The other ingredients are: *Lactose, microcrystalline cellulose, sucralose, croscarmellose sodium, talc, magnesium stearate, mango flavour, sun-set yellow lake (E110), povidone K30, colloidal silicon dioxide.*

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9. Manufacturer

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10. Product registration holder

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