

VECTRINE[®]

Capsule-Dry syrup

**Compositions:**

VECTRINE[®] 300
Each capsule contains
Erdosteine 300 mg

VECTRINE[®] Dry syrup
Each 5 ml contains
Erdosteine 175 mg

Pharmacology:

Erdosteine pharmacologically acts as a bronchial mucus fluidifying agent.

Pharmacotherapeutic:

Erdosteine is classified under the mucolytic drugs.

Pharmacodynamics:

Erdosteine besides its property of fluidifying bronchial mucus thus facilitating expectorations, shows effects as antagonizing the formation "in loco" of free radicals and as contrasting the action of elastase enzyme. Pharmacological studies show that erdosteine, as such, does not possess these properties but only after metabolization, transform into active metabolites which have the chemical -SH groups. These metabolites break the -SH groups and bringing about a reduction in the mucus elasticity and viscosity thus facilitating the expectoration. The chemical -SH groups, distinctive of this activity, are chemically blocked and become free only after metabolization or in alkaline moiety. This property guarantees a good tolerability without bad tastes and without mercaptanic regurgitations and with good gastric tolerability.

Pharmacokinetics:

- Erdosteine is rapidly absorbed after oral administration, after a single oral dose, the T_{max} is 1.2 hours.
- Erdosteine is rapidly metabolized into at least 3 active metabolites containing free thiol groups, which tentatively are: N-thiodiglycyl-homocysteine (metabolite I), N-acetyl-homocysteine (metabolite II), and homocysteine (metabolite III). The elimination half-life of erdosteine is 1.4 hours on the average, and that of the metabolite I and II of 1.2 and 2.7 hours, respectively.
- Multiple treatments do not modify the pharmacokinetics of erdosteine.
- Age does not change the pharmacokinetics of erdosteine and of its metabolites.
- In the elderly patients suffering from renal failure, whose creatinine clearance is comprised between 25 and 40 ml/minute, the pharmacokinetic characteristics of erdosteine and its metabolites are not significantly different from those of the healthy elderly patients.

Indications:

Mucolytic, fluidifying agent in acute and chronic airways affections.

Contraindications:

- Known individual hypersensitivity to the product.
- In patients suffering from hepatic cirrhosis and deficiency of the cystathionine-synthase enzyme.
- Phenylketonuria, due to the presence of aspartame, only for the granulate in suspension.
- In patients with severe renal failure (creatinine clearance <25 ml/minute).

Dosage and administrations:**Dosage**

VECTRINE[®] capsule:
1 capsule, 2-3 times a day.

VECTRINE[®] dry syrup:

Children 15-19 kg: 5 ml, 2 times a day.
Children 20-30 kg: 5 ml, 3 times a day.
Children >30 kg and adults: 10 ml, 2 times a day.

Administrations:

Prepare suspension at time of dispensing by adding 48 ml of water. Once reconstituted, the suspension must be used within 7 days.

Warnings and precautions:

- The product in granulates (suspension) contains sucrose, keep this into consideration in case of diabetes or low-calorie diets.
- Pregnancy and lactation: the safety of erdosteine in pregnancy has not been established and therefore as with all new drugs, its use is not recommended in pregnant women and also during lactation.
- Effects on ability to drive and use machines: no effects have been reported.

Adverse reactions:

No gastrointestinal or systemic adverse reactions due to the drug have been observed. If undesirable effects occurred, should be informed to the physician.

Drug interaction:

No harmful interactions have been observed with other medicaments and the drug can be administered together with antibiotics, bronchodilators (theophylline, β_2 -mimetics, cough sedatives, etc).

Overdosage:

With dosages exceeding the suggested ones (900 mg/day): sweating, vertigo, and flushing have been observed.

Presentations:

VECTRINE[®] 300. Box, 2 blisters x 10 capsules
VECTRINE[®] Dry syrup. Box, 1 bottle x 60 ml

ON MEDICAL PRESCRIPTION ONLY.

STORE AT TEMPERATURE BELOW 30°C, PROTECT FROM LIGHT.

KEEP OUT OF REACH OF CHILDREN.

SHAKE WELL BEFORE USE.

Manufactured by
PT Dexa Medica
Jl. Jend. Bambang Utoyo No.138
Palembang-Indonesia

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EDMOND PHARMA s.r.l
Italy

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