

RECTALIS

Rectal Cream



Composition:

Each 1g of Rectalis Rectal Cream contains:
Lidocaine HCl 15 mg and Nifedipine 3 mg.

Pharmacological Classification:

Topical Anesthetics and Calcium Channel Blockers.

Intended Use (Common Use of the Drug):

Treatment of anal fissures and hemorrhoids.

Mechanism of Action:

Rectalis Cream is a medicine with the combination of Nifedipine and Lidocaine. Nifedipine works by inhibiting the influx of calcium into the smooth muscles and causes relaxation of the muscles. Lidocaine works by blocking pain signals from the body to the brain. Thus, the combination is better effective for the treatment of anal fissures.

Pharmacokinetics:

Absorption: The rate and extent of absorption depends upon concentration and total dose administered, the specific site of application, skin and/or mucosa condition, and duration of exposure.

Distribution: Lidocaine has a total plasma clearance of 0.95 L/min and a volume of distribution at steady state of 91 L. 60 to 80 % of lidocaine is protein bound.

Nifedipine is highly bound to human plasma proteins (range from 92 to 98%) and is concentration-dependent, with a relatively low volume of distribution.

Metabolism: Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Only 2% of lidocaine is excreted unchanged. Up to 70% appears in the urine as 4- hydroxy- 2,6-dimethylaniline.

Nifedipine is extensively metabolized in the liver (to three highly water-soluble and pharmacologically inactive metabolites).

Elimination: Lidocaine has an elimination half-life of 1.6 h. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

60 to 80% of a Nifedipine dose is excreted as water-soluble, inactive metabolites in the urine. The remainder is excreted in the feces in metabolized form, most likely as a result of biliary excretion. The main metabolite (95%) is the hydroxycarboxylic acid derivative.

Indications:

- Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.

- Rectalis cream is indicated for treatment of anal fissures and proctologies generally associated with anal sphincter hypertonia.

Contraindications:

- Hypersensitivity to the active ingredients, particularly to Lidocaine (and other local anesthetics with a similar amide type structure) or to any other excipient.

- Severe hypotension and cardiac insufficiency.

Side Effects:

- Like all medicines, this one can cause side effects, although not everyone experiences them.

- Reactions like pain, a burning sensation, itchiness, hyperemia and bleeding could occur locally. These effects decrease when the treatment is stopped.

- Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & Precautions:

- Rectalis cream is recommended for external use only. Therefore, avoid contact with eyes, ears, nose and mouth.

- You must inform your doctor if you have lung, kidney, or liver problems before using Rectalis cream to avoid worsening the condition.

- You should tell your doctor if you suffer from any skin irritation, such as burning or itching.

Drug and Food Interactions:

- Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

- Treatment with Rectalis may increase the effect of anti-hypertensive drugs due to the presence of Nifedipine.

- Propranolol prolong the plasmatic half-life of Lidocaine and increases the plasmatic levels of Nifedipine.

- Cimetidine may increase the plasmatic levels of Nifedipine and Lidocaine.

- The simultaneous administration of Rectalis for rectal use in patients in treatment with Digoxin may increase the plasmatic levels of Digoxin.

Pregnancy & Lactation & Fertility:

Pregnancy: Rectalis Cream is not recommended to be used during pregnancy due to the risk of serious side effects to your foetus.

Lactation: Rectalis Cream is not recommended to be used during breastfeeding. Consult your doctor before using this medicine.

Fertility: An animal study has shown that nifedipine is associated with reversible adverse effects on sperm function. No changes in fertility have been reported with lidocaine.

Effects on ability to drive and use machines:
No effects that could influence the capacity to drive and to operate machinery.

Method of use:

- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

- For endorectal and perianal applications.

- Apply the cream twice a day for at least three weeks.

Method of administration:

Lie on your left side, unscrew the tube cap and screw the cannula. Squeeze a small amount of cream to lubricate the cannula and insert it into the anus (up to 1 cm inside the anus). Squeeze 1 cm from the tube (each 1 cm equals about 2.5-3 g of cream). Stay on your left side for 3-5 minutes after application.

- Inform your doctor or pharmacist if you forget to apply the cream and before stopping its use.

Overdoses/Toxicity/methods of treatment:

An overdose of Rectalis cream may cause symptoms such as headache, itching, and burning at the application site.

Consult a doctor immediately if an overdose of the cream is suspected.

Physical Properties:

Yellow cream, homogeneous, free from foreign matter.

Storage Conditions:

Store at a temperature below 25° C.

Keep out of reach of children.

Keep tube tightly closed.

Packaging:

Each Rectalis cream carton box contains Aluminum Tube of 20 g, special applicator attached

- A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
- KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
- Council of Arab Health Ministries - Union of Arab Pharmacists

Revapharma for Pharmaceutical Industries - Idlib - Syria

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