

REVACINOLON

Suppositories & Rectal Cream & Ointment



Composition:

Each REVACINOLON Suppository contains:

Fluocinolone Acetonide	100 mcg.
Lidocaine HCl	40 mg.
Bismuth Subgallate	100 mg.
Menthol	5 mg.

Each 1 g of REVACINOLON Rectal Cream or Ointment contains:

Fluocinolone Acetonide	100 mcg.
Lidocaine HCl	20 mg.
Bismuth Subgallate	50 mg.
Menthol	2.5 mg.

Pharmacological Classification:

Antihemorrhoidal Drugs.

Intended Use (Common Use of the Drug):

Treatment of hemorrhoids and anal pruritus and proctitis.

Mechanism of Action:

- Fluocinolone acetonide is a corticosteroid that inhibits the inflammatory response to a variety of stimuli including multiple inflammatory cytokines. It prevents edema, fibrin deposition, capillary dilation, and scar formation associated with inflammation.
- Lidocaine hydrochloride has a local anesthetic effect, acting on sodium channels on the inner surface of nerve cell membranes, relieving pain and discomfort in affected areas.
- Bismuth Subgallate exert a protective action on mucous membranes. They have a mild astringent effect and have antiseptic and antihemorrhagic properties.
- Menthol provides a cooling sensation when applied to the skin, which helps to relieve pain in the subcutaneous tissues.

Pharmacokinetics:

REVACINOLON has a local action with minimal of systemic effects. Fluocinolone can be absorbed from normal intact skin, and systemic absorption is less than 0.1 ng/ml. It is metabolized primarily in the liver and excreted by the kidneys. Lidocaine is partially absorbed but plasma levels will be low. It is metabolized in the liver and about 90% of a given dose undergoes de-ethylation. The rest of the active ingredients in REVACINOLON product exert their therapeutic effect without systemic absorption.

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.
- REVACINOLON are used to relieve symptoms of pain, swelling and irritation associated with hemorrhoid, anal fissures and anal pruritus.

Contraindications:

- This medicine should not be used if you are hypersensitive to the active substance or any of the excipients.
- Severe viral or bacterial infections for which appropriate antimicrobial treatment is not provided.
- Children under 2 years of age.

Side Effects:

- Like all medicines, this one can cause side effects, although not everyone experiences them.
- Very rarely increased irritation may occur at the site of application
- Inform your doctor or pharmacist if you experience any side

effects not listed in this leaflet.

Warnings & Precautions:

- REVACINOLON should be used with caution and under the supervision of a physician in the event of:
 - Use for more than 7 days due to the possibility of systemic absorption.
 - Persistence or worsening of symptoms.
 - People with severe rectal bleeding.
 - Use in children under 12 years of age.
 - It is recommended to separate topical preparations by two hours.

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.
- Concurrent use with other corticosteroid preparations, either topical or oral, may increase the potential for systemic effects.

Pregnancy & Lactation & Fertility:

Pregnancy: There is no conclusive evidence of the safety of REVACINOLON during pregnancy.

Lactation: There is no conclusive evidence of the safety of REVACINOLON during breastfeeding.

Fertility: Its effect on fertility after topical application in humans has not been studied.

Effects on ability to drive and use machines:

REVACINOLON topical has no or negligible influence on the ability to drive and use machines.

Method of use:

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

Adults and children 12 years and over:

Suppositories: One rectal suppository taken in the morning and evening and after each bowel movement, not exceeding three suppositories per day as a maximum.

Cream or Ointment: may be intrarectally applied by using the special applicator provided.

The application of cream or ointment is 2 - 3 times daily.

Cream or Ointment should be gently applied on the affected area after using warm anal bath.

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

Overdoses/Toxicity/methods of treatment:

No cases of overdose have been reported.

Physical Properties:

- Yellow, smooth, uniform, free from foreign matter Cream or Ointment.
- Yellow suppositories.

Storage Conditions:

Ointment and Cream: Store at a temperature below 30° C. Keep tube tightly closed.

Suppositories: Store at a temperature below 25° C.

Keep out of reach of children.

Packaging:

Each REVACINOLON suppositories carton box contents 10 suppositories in two PVC/PE strips.

Each REVACINOLON cream or ointment carton box contains Aluminum Tube of 20 g, special applicator attached.

- A medicament 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 medicament.
- 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 Pharmacies

Revapharma for Pharmaceutical Industries - Idlib - Syria

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