PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

ANTROLIN
Cream for rectal use

1) NAME OF THE MEDICINE, ITS FORM AND STRENGTH:

Name of the medicine: Antrolin.

The form: Cream for rectal use.

Composition of active ingredients and their concentration per dosage unit:
Nifedipine 0.3% and Lidocaine Hydrochloride 1.5%.

For a list of the inactive and allergenic ingredients in the medicine - see section 6.

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

What is the medicine intended for? The medicine is intended for treatment of an anal (rectal) fissure and anal symptoms caused by anal sphincter hypertonia.

Therapeutic group and therapeutic action:
Nifedipine: smooth muscle relaxant (calcium channel blocker).
Lidocaine: local anesthetic (from the "Caine" family).

2) BEFORE USING THE MEDICINE:

X Do not use the medicine if:
- You are sensitive (allergic) to the active ingredients, to other local anesthetics with a similar structure or to any of the additional ingredients contained in the medicine. The active ingredients appear in section 1 and the inactive ingredients are detailed in section 6.
- You are suffering from low blood pressure or cardiac insufficiency.

Special warnings regarding use of the medicine:

! Before treatment with the medicine, tell the doctor if:
- You are suffering from an inflammation, bruise or injury in the anal or rectal area. Use of the medicine in such cases may cause excessive absorption of the active ingredients into the body.
- You have diabetes.
- You have impaired liver function.
- You have impaired kidney function.
- It may be necessary to monitor blood pressure (especially arterial blood pressure) before and during use of the medicine.

Do not apply in the eyes and avoid contact of the cream with the eyes. In case of contact with the eyes, rinse thoroughly with running water and seek medical care if necessary.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist. In particular, if you are taking: Beta-blockers, medicines to reduce blood pressure, propranolol, cimetidine, digoxin.

! Pregnancy and breastfeeding:
The efficacy and safety of use of both of the active ingredients in the medicine during pregnancy and breastfeeding have not been established, but they are not expected to cause harm. If you are pregnant (especially in the first trimester), planning a pregnancy or breastfeeding, consult a doctor.

! Important information about some of the ingredients of the medicine:
- The medicine contains the preservatives sodium methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause sensitivity or an allergic reaction, which may occur some time after using the medicine.
- The medicine contains the inactive ingredients propylene glycol and cetostearyl alcohol, which may cause localized skin irritation (contact dermatitis).

3) HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally: apply twice a day.
Do not exceed the recommended dose.
Method of administration: Do not swallow. The medicine is intended for external use only in the anus and rectum.

Who is the medicine intended for: The medicine is intended for adults over the age of 18.

Instructions for use:
- Thoroughly clean and dry the anal/rectal area.
- Lie down in a comfortable place and tilt your body towards the left.
- Remove the cap from the tube and in place of it screw on the applicator (plastic tube) with the cover.
- Release a small amount of cream to lubricate the outer part of the applicator.
- Insert the tip of the applicator into the rectum and gently press the tube to insert the cream. Release approximately 1 cm of cream (equivalent to approximately 2.5-3 grams of cream).
- Take the applicator off of the tube and rinse it with hot water and soap.
- When finished using – close the tube with the cap.
- Wash your hands after using the medicine.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult a doctor.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. The area may not have fully healed, even if you feel otherwise, and it is therefore important to complete the treatment according to the doctor's instructions.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS:
As with any medicine, use of this medicine 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.

In very rare cases, hypersensitivity reactions occurred after topical use of medicines containing lidocaine (in very severe cases, anaphylactic shock-type allergic reactions occurred). **Discontinue use of the medicine and refer to a doctor immediately!**

Local side effects at application site (anus/rectum): pain, burning sensation, itching, accumulation of large amounts of blood in the treated area (hyperemia) and localized bleeding. These effects decrease after discontinuing treatment with the medicine.

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs 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 must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (Exp. Date) that appears on the package/tube/bottle/carton/label. The expiry date refers to the last day of that month.

Storage conditions: Store tightly closed in the package, at a temperature below 25°C.

After first opening the tube: The medicine can be used for up to 30 days (one month).

6) FURTHER INFORMATION:
In addition to the active ingredients, the medicine also contains:
White Vaseline (= Paraffin, White Soft), Propylene Glycol, Semi-Synthetic Liquid Glycerides (= Triglycerides, Medium-Chain = MCT), Polyethylene Glycol Stearate (= Macrogol Stearate = PEG Stearate), Cetostearyl Alcohol, Glycerol Monostearate, Sodium Methyl Parahydroxybenzoate (= Sodium Methylparaben), Propyl Parahydroxybenzoate (= Propylparaben), Purified Water.

What the medicine looks like and the contents of the package: The medicine looks like a yellow cream, with a homogenous texture and characteristic scent.
The cream is packaged in a metal tube, closed with a plastic screw-cap. Each tube is packaged in a carton box, to which is also attached an applicator (plastic tube) with a cover, that can be screwed on instead of the cap.

Package size: A tube containing 30 grams of cream.

Registration holder: Super-Pharm (Israel) Ltd., P.C. 510753551, 16 Aryeh Shenkar St., Herzliya 4672516.

Manufacturer: New Fa Dem Pharmaceutical and Chemistry S.r.l., Guigliano in Campania (NA), Italy.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 160.31.34663.00

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