

PACKAGE LEAFLET: Information for the patient

PRO-SYNAL

Rectal cream – (0.1 mg + 20 mg) / g

(Fluocinolone acetonide, Lidocaine hydrochloride)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pro-Synal is and what it is used for
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4. Possible side effects
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1. WHAT PRO-SYNAL IS AND WHAT IT IS USED FOR

Pro-Synal rectal cream is a specific combination of fluocinolone acetonide with lidocaine hydrochloride suitable for the pharmaceutical treatment of hemorrhoids and rectal area pathologies.

Fluocinolone acetonide is a corticosteroid for local use, with strong anti-phlegmonic, antipruritic, and vasoconstrictive activity. Lidocaine hydrochloride is a strong anesthetic and actually it is widely used for anesthesia in phlegmonic mucosa.

Pro-Synal attenuates treatment of hemorrhoids and of the anus-rectum area; pain and itching are removed or gradually reduced. Patients feel the coolness and tranquility for hemorrhoids.

Pro-Synal is used to treat internal and external hemorrhoids and anus eczema.

2. BEFORE YOU USE PRO-SYNAL

Pro-Synal rectal cream must not be used:

- if you are hypersensitive to corticosteroids, including fluocinolone acetonide, and to local anesthetics, including lidocaine hydrochloride, or to any of the excipients of the drug, because allergic reactions may appear, including anaphylaxis;
- in specific skin lesions (syphilis, tuberculosis);
- in severe renal diseases;
- in some viral diseases;
- in hemorrhage;
- in conditions when getting vaccinated.

Take special care with Pro-Synal

Treatment with antibiotics is recommended in cases of possible infections and when the infection cannot be controlled, it is recommended to stop the treatment with rectal cream until the infection is totally controlled.

It should not be used longer than three weeks without first consulting a specialist.

Treatment of children and adolescents is not recommended as no clinical studies have been conducted. However, it may be used only under strict medical control.

While using this preparation with corticosteroid for a long period of time, the patients should be examined regularly and perform some tests, to be checked for possible hypertension, glucosuria, hypokalemia, gastric and mental disorders.

Taking other medicines

There are no data about interactions with other medicines. Anyway, tell your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Pro-Synal rectal cream if you are given another drug during treatment.

Pregnancy and breastfeeding

Ask for medical advice or ask your pharmacist before using this drug.

During pregnancy, use of Pro-Synal rectal cream often, for long periods of time and in large amounts, should be avoided.

Pro-Synal rectal cream should not be used during breastfeeding as there are no data regarding safety.

Driving and using machines

This drug has no effect on the ability to drive or use machines.

Important information about some of the excipients of Pro-Synal

Contains methylhydroxybenzoate and propylhydroxybenzoate, which may cause allergic reactions (possibly delayed).

Contains 50 mg propyleneglycol in 1 g rectal cream.

Contains approximately 5 mg ethanol in 1 g rectal cream, which may cause burning sensation on damaged skin.

Contains butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the mucous membranes.

3. HOW TO USE PRO-SYNAL

Your doctor will inform you about when and how much Pro-Synal you should use. It is important to follow the doctor's instructions precisely and never change the dose yourself, no matter how you feel. Ask your doctor or pharmacist if you are not sure about the dose that you should use and when you should use it.

Pro-Synal rectal cream may be used as follows:

The usual total duration of treatment is 1-3 weeks. A small amount of cream should be applied gently to the affected area, usually two to three times a day. This cream may be applied also in the rectum by using an applicator (of tube shape).

Treatment of children and adolescents is not recommended as no clinical studies have been conducted. However, it may be used only under strict medical control.

If you use more Pro-Synal

If you use more Pro-Synal than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to use Pro-Synal

If you forget to use a single dose of Pro-Synal, use it as soon as you can. If it is almost time for the next dose, use it and skip the forgotten dose. Do not use a double dose of Pro-Synal to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pro-Synal can cause side effects, although not everybody gets them.

Most of the side effects are dose related and disappear when the dose is reduced or the treatment is discontinued. Some of the side effects can occur in the beginning of the treatment and disappear spontaneously during treatment.

This formulation generally is well tolerable. Rarely burning sensation and itching may occur, which disappear during the treatment. Pro-Synal practically does not cause redness or sensible areas. Treatment with the necessary antibiotics is recommended in cases of possible local or general infections.

General side effects can appear after using this preparation for a long period of time such as: decrease of plasma cortisol levels, Cushing syndrome and adrenocortical suppression. It may cause also local side effects after long-term treatment such as: change of the clinical feature, fungal or microbial local infections, hypersensitivity reactions, hypertrichosis.

Talk to your doctor or pharmacist, if you get any side effects not listed in this leaflet.

5. HOW TO STORE PRO-SYNAL

Store in a dry and cool place, at a temperature not higher than 25°C!

It should be protected from light and humidity.

Do not freeze!

Do not use after the expiry date.

Keep it in a safe place, out of the sight and reach of children, as it may harm them.

6. FURTHER INFORMATION

What Pro-Synal rectal cream contains

The active substances are fluocinolone acetonide and lidocaine hydrochloride.

1 g rectal cream contains 0.1 mg fluocinolone acetonide and 20 mg lidocaine hydrochloride.

The excipients are: propylene glycol, white soft paraffin, liquid paraffin, methyl hydroxybenzoate, propyl hydroxybenzoate, PEG - stearate glycol stearate, menthol, macrogol glycerol oleate, disodium edetate, ethanol, butylated hydroxytoluene, purified water.

Contents of the pack

Box with one tube of 15 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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