

SUMMARY PRODUCT CHARACTERISTIC (SPC)

PROCTOMED

Cream for rectal use

1. Trade name – Proctomed

International non-property name – Phenylephrine, Cinchocaine HCl (Dibucaine), Shark liver oil

2. Quantitative and Qualitative Composition

Each gram contains:

active ingredients: phenylephrine hydrochloride - 2.5 mg, cinchocaine HCl (Dibucaine) - 10 mg, shark liver oil - 30 mg;

For a full list of excipients see section 6.1.

3. Pharmaceutical form

Cream for rectal use.

White to off white homogenous cream.

4. Clinical Particulars

4.1 Therapeutic indications

- external and internal hemorrhoids.,
- anal fissures,
- anal itching,
- pain relief after proctologic operations.

4.2 Posology and Method of Administration

It is best to use Proctomed after defecation.

Adults and children over 12 years: before using the medication to the affected area carry out hygiene, namely, clean the affected area by gently patting with a cleaning tissue. Dry the area by gently patting with a piece of dry tissue or clean cloth. Remove the protective cover from the applicator tip, attach the applicator tip to the medication tube, and lubricate the applicator tip. Gently insert the applicator tip into the rectum and apply a small amount of this medication morning and evening. Apply some medication to the external area around the rectum as well. Apply the preparation to the affected area two times a day, morning and night. After each use, clean the applicator tip well and replace the protective cover. In conditions with severe pain, the cream may be applied up to 4 times daily.

Patients should be advised to consult a clinician if the anorectal condition worsens or does not improve within 4 weeks of treatment, or if bleeding occurs.

4.3 Contraindications

- Proctomed cream should not be used in individuals with known hypersensitivity to each ingredient.
- Children up to age 12 years.
- Thromboembolic disease.

- Granulocytopenia.

4.4 Precautions for Use and Special Warnings

You should continue to use Proctomed cream at least for one week, but less frequency (1 time daily) to avoid from recurrences, even with the completed disappearance of the symptoms.

However, the duration of treatment should not exceed 4 weeks.

Unless otherwise directed by a clinician, patients should not receive Proctomed cream for self-medication of hemorrhoidal symptoms if they have cardiac disease, high blood pressure, thyroid disease, diabetes mellitus, or difficulty in urination secondary to prostatic hyperplasia. Patients also should be advised to consult a clinician before initiating self-medication with an anorectal preparation of the preparation if they currently are receiving an antihypertensive agent or antidepressant (e.g., monoamine oxidase inhibitor [MAOI] inhibitor).

If rectal bleeding occurs during use of Proctomed cream for pain, itching, and burning of hemorrhoids or if rash, irritation, swelling, pain, bleeding, or other symptoms develop or increase during use of Proctomed cream, the preparation should be discontinued and a physician consulted.

Tell your doctor if you are pregnant before using this medication. It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding. If you miss a dose, use it as soon as you remember.

If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

In case of bleeding, impairment of the condition or in the absence of therapeutic effect within 7 days stop taking the preparation and consult with doctor.

In case of accidental oral administration of the drug (e.g. ingestion of a few grams of the cream) is probably appearance of systematic side effects, especially from the side of cardiovascular system – a reduction up to cardiac arrest, central nervous system – convulsions, respiratory suppression up to stop.

It's necessary to avoid from accidental contact of Proctomed cream with eyes. After using it is recommended to wash hands carefully.

This medicine contains Propylene glycol

Propylene glycol can cause skin irritation.

This medicine contains methylparaben and propylparaben

May cause allergic reactions (possibly delayed).

Patient information

Call your doctor right away if you notice any of these side effects:

- Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing.
- Bleeding from your rectum.
- No improvement, or worsened symptoms after using the medicine for 4 weeks.
- Pain in your rectum when using the medicine applicator.

4.5 Drug interactions

Tell your doctor of all prescription and nonprescription medication you may use, especially: high blood pressure medicine, MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid,

moclobemide, phenelzine, procarbazine, selegiline, tranylcypromine), antidepressants (e.g., fluoxetine, sertraline).

With simultaneous use of the preparation reduces the effect of antihypertensive drugs.

Hypertensive crisis may develop when concomitant administration with antidepressants (e.g., fluoxetine, sertraline) and MAO inhibitors.

Do not start or stop any medicine without doctor or pharmacist approval.

4.6 Pregnancy and Breast-Feeding

Proctomed used during pregnancy and lactation (breastfeeding) only if the expected benefit for mother outweighs the potential risk for the fetus or child.

4.7 Possible Side Effects

Local reactions: redness, itching, swelling.

Allergic reactions are possible.

No side effects are expected to occur. If side effects occur, notify your doctor promptly. If you notice any of the following unlikely but very serious side effects, stop using this medication and consult your doctor or pharmacist immediately: bleeding from the rectum, increased pain (after inserting the applicator tip). If you notice other effects not listed above, contact your doctor or pharmacist.

Phenylephrine

When used in recommended dosages for local effect in anorectal disorders (e.g., hemorrhoids), adverse systemic effects of vasoconstrictors such as phenylephrine generally are minimal. Such effects, although unlikely, can include blood pressure elevation, cardiac arrhythmia or irregular heart rate, CNS disturbance or nervousness, tremor, sleeplessness, and aggravation of hyperthyroid symptoms.

Based on observations with local use for nasal congestion, prolonged local use of excessive anorectal dosages of vasoconstrictors will likely lead to rebound vasodilation and congestion.

Less commonly, prolonged local use of excessive anorectal dosages of vasoconstrictors can lead to anxiety and paranoia.

Phenylephrine reportedly is less likely than other topical vasoconstrictors (e.g., ephedrine, epinephrine) to cause local irritation. Contact dermatitis has been reported following topical application of certain formulations of vasoconstrictors.

The possibility that topical anorectal application of vasoconstrictors if absorbed systemically in adequate amounts could interact with monoamine oxidase (MAO) inhibitors resulting in potentiated hypertensive effects should be considered. Such hypertensive potentiation could result in serious, potentially fatal effects such as cerebral hemorrhage or stroke.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Arpimed "LLC" by going to www.arpimed.com and fill out the appropriate form "Report an adverse reaction or inefficiency of drug". Hotline number: (+374 55) 05 79 86. And by using Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan "CJSC", going to the site: www.pharm.am in "Report about adverse effect of medicine" section and fill out the

"Report of adverse reaction or manufacturing problem of medicinal product". Hotline numbers: +37410200505; +37496220505.

4.8 Overdose

Symptoms may be associated with systemic absorption of dibucaine (which is a component of the preparation) and includes drowsiness, restlessness, agitation, and in severe cases - seizures, very rarely - methemoglobinemia (manifested impaired breathing and cyanosis). With a significant excess of recommended single and daily doses of the shark liver oil's components may develop an increased propensity to blood clotting.

Treatment: in case of methemoglobinemia – i/v of methylene blue.

5. Pharmacological Properties

5.1 Pharmacodynamics

Pharmacological group and ATC code:

Antihemorrhoidal; C05AX03.

Combined preparation for the topical treatment of hemorrhoids. Proctomed cream contains shark liver oil, a natural source of vitamin A, which promotes wound healing and tissue repair thus relieving symptom accompanying the healing process. Shark liver oil acts also as an emollient and protectant that provides a physical barrier to irritation by foaming a protective layer over the mucous membranes and the skin of the anal region, thereby preventing excessive water loss from the tissues. Shark liver oil has anti-inflammatory, hemostatic, wound healing, immunomodulatory and anti-cancer effect due to its composition; fat-soluble vitamins and alkoxy glycerol.

Phenylephrine is adrenomimetic, has a local vasoconstrictor effect, which helps to reduce exudation and reduce swelling, itching, serous discharge with hemorrhoids and other anorectal diseases zone. Phenylephrine is used to provide temporary symptomatic relief of external or internal hemorrhoids. When applied rectally to the anorectal area, phenylephrine stimulate α -adrenergic receptors in the vascular beds with a resultant temporary constriction of arterioles and a modest and transient reduction in congestion (swelling) of hemorrhoidal tissues. Phenylephrine also may relieve anorectal pruritus, discomfort, and irritation, possibly in part secondary to some weak local anesthetic action; the mechanism of this local anesthetic effect is unknown.

Phenylephrine also helps to prolong the duration of dibucaine-induced local and regional anesthesia. Phenylephrine also may relieve pruritus associated with histamine release. However, Phenylephrine is expected to provide only partial relief of pruritus associated with hemorrhoids, and there are more effective agents for relief of anorectal itching. The presence of other ingredients in the formulation (e.g., dibucaine, shark liver oil) may provide additional relief of these and other anorectal symptoms (e.g., discomfort, pain, burning) associated with hemorrhoids.

Dibucaine is one of the most potent and long-acting local anesthetics. Dibucaine causes rapid relief of pain and itching associated with painful hemorrhoids and other anal conditions.

6. Pharmaceutical Particulars

6.1 List of Excipients:

- cetyl alcohol
- glyceryl monostearate
- vaselin (white petrolatum jelly)

propylene glycol
polysorbate 60
methylparaben
propylparaben
water purified

6.2 Special precautions for storage

Store in a dry place, out of the reach of children, at a temperature below 25°C. Protect from light.

6.3 Shelf life

3 years. Do not use the medicine after the expiry date.

6.4 Nature and content of container

20 g of cream is filled into aluminum tube (inside package). The tube packed and inserted with the rectal applicator and leaflet into cardboard box (outer package).

7. Manufacturer

“ARPIMED” LLC

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8. Marketing authorisation holder

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9. Date of first authorisation/renewal of the authorisation

29.05.2008 (Date of first authorisation).

Date of revision of the text