Procto-Glyvenol®

Cream and Suppository

Composition:
Active ingredients: tribenoside, lidocaine/ lidocaine hydrochloride.
Cream: Preservatives: methyl (E218) and propyl (E216) parahydroxybenzoate, other excipients.
Pharmaceutical forms and quantity of active ingredient per unit 1 suppository (2 g) contains 400 mg of tribenoside and 40 mg of lidocaine. The suppositories are yellowish-white and torpedoshaped.
100g of cream contain 5% tribenoside and 2.12% lidocaine hydrochloride.
1 g of cream contains 50 mg of tribenoside and 21.2 mg of lidocaine hydrochloride. The cream is white and homogenous.

Indications/Possible uses:
Local treatment of external and internal haemorrhoids.

Posology/Method of administration
Adults: During the acute phase of the disorder, apply the cream or suppository morning and evening; subsequently, reduce to one application of cream or one suppository a day. 30g of cream (1 tube) are enough for approximately 20–30 applications.
Avoid contact with the eyes.
Intended for adult use only; not suitable for children.

Contraindications
Hypersensitivity to the active ingredients or excipients, according to composition.

Warnings and precautions:
Where there is bleeding in the anal area or where faecal blood is suspected or in the onset of other unusual symptoms, a medical examination with a view to diagnosis is advised.
Where symptoms appear for the first time, self-medication should not last longer than 2 weeks. Repeat treatment should only take place following diagnosis confirmed by a doctor.
Procto-Glyvenol should be used with caution in patients with severely impaired liver function.
There is no clinical experience in children.
Procto-Glyvenol cream contains cetyl alcohol, which may lead to local skin reactions (e.g. contact dermatitis). The cream also contains methyl and propyl parahydroxy-benzoate; these substances may trigger allergic reactions (possibly delayed).

Interactions
No interaction studies have been performed.

Pregnancy/Breastfeeding:
There is not enough data concerning use in pregnant women.
No animal experiments exist on tribenoside or tribenoside in combination with lidocaine. Also, it is not known whether tribenoside crosses the placental barrier.
Lidocaine shows some toxic effect on the embryo.
Given these conditions, Procto-Glyvenol should not be used during pregnancy, particularly during the first three months, except when absolutely necessary.
Lidocaine can enter maternal milk; the advantages to the mother will have to be weighed against the risks to the child. As a precaution a choice is made between ending treatment and ending breastfeeding.

Effect on ability to drive and to operate machinery:
No relevant studies have been performed.

Adverse events
Undesirable effects are listed below, classified by system organ class and frequency. Frequencies are defined as follows: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) very rare (<1/10,000), not known (cannot be estimated from the available data).

Immune system: Very rare: anaphylactic reaction
Heart: Very rare: Cardiovascular disorders
Skin: Rare: urticaria, Very rare: angioedema
Respiratory organs: Very rare: bronchospasm
Reactions at site of application
Rare: pruritus, rash, pain.
Very rare: Facial oedema

Overdose
No cases of overdosing have been reported.
In the event of accidental oral ingestion, gastric lavage is recommended, together with symptomatic treatment as well as general supportive measures.

Properties/Effects
ATC Code: C05AD01
The effect of tribenoside is based on the one hand on reducing capillary permeability and increasing vascular tone, and on the other hand on its local properties as an anti-inflammatory and antagonist to a whole series of endogenous substances that play a role as mediators in the occurrence of inflammation and pain.
Lidocaine is a local anaesthetic agent and relieves the pain, burning and itching caused by haemorrhoids.

Pharmacokinetics
Absorption
Systemic bioavailability of tribenoside in suppository form is only 30% compared to oral administration (capsules). Approximately 2–20% of tribenoside is absorbed through the skin from Procto-Glyvenol cream. 2 hours following rectal administration of a suppository (400 mg of tribenoside), maximum plasma concentrations of 1µg/ml of tribenoside and its metabolites are found. Lidocaine is readily absorbed from mucous membranes, but only moderately from intact skin. After rectal administration, the bioavailability of lidocaine is approx. 50%. Peak plasma concentrations of 0.70 µg/ml are reached 122 minutes after administration of a suppository of 300 mg lidocaine.

Distribution
The binding of lidocaine to plasma proteins, particularly alpha 1-acid glycoprotein, is variable and dependant on concentration (approximately 60–80% at concentrations of 1–4 µg/ml).

Metabolism
In the body, tribenoside is highly metabolised. Lidocaine is rapidly metabolised in the liver.

Elimination
Tribenoside: After insertion of a suppository 20–27% of the dose is excreted in the urine in the form of metabolites.
Lidocaine: Less than 10% is excreted unchanged; the metabolites are excreted in the urine.

Comments regarding storage:
Store Procto-Glyvenol out of the reach of children.
Do not Store above 30 C.
The medication must not be used after the date following the wording “EXP” on the packaging.

Packs:
Suppositories: 10 pieces
Cream: 30 gm. tube

Manufacturer:
Cream: Novartis Consumer Health, Nyon, Switzerland.
Suppository: Delpharm Huningue, France. For: Novartis Consumer Health, Nyon,Switzerland.
Information up-date: (revision) July 2012.

(THIS IS A MEDICAMENT)
- Medicament is a product which affects your health, and its 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 are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children

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