

of hemorrhoidal seizures (fluxion) and thrombosis (pain, anal itching and burning, sensation of mass, constipation, among others), mostly of mild intensity, which resolve spontaneously without drug treatment.

DOSAGE AND METHOD OF ADMINISTRATION

Remove the suppository from the blister and, holding it on the opposite side to the pointed end, carefully insert it through the anus. Administer rectally a suppository every 8 hours until completing 4 units. If necessary, treatment with additional units of **Proctokinasa**® can be continued, up to a maximum of 6 to 8 suppositories.

INTERACTIONS WITH OTHER MEDICINES

The use of antifibrinolytics inhibits the action of thrombolytics.

USE IN PREGNANCY AND LACTATION

The use of **Proctokinasa**® is not recommended during pregnancy or lactation.

OVERDOSE

An overdose of **Proctokinase**® increases the risk of rectal bleeding.

Center for Genetic Engineering and Biotechnology

Distinctive company of Cuban biotechnology which develops, produces, markets and exports innovative products, for key areas of the biomedical, veterinary, agricultural, aquaculture and industrial sectors, for one health. It has a portfolio of research and development (R&D) projects and products, protected by patents. Its more than 30 products marketed in more than 35 countries, include first and only drugs of its kind, to treat diseases that do not have other effective therapeutic solutions. Several of its medicines are inserted into national programs to offer comprehensive health care. We work with social responsibility and in harmony with the environment.

MCIGB CENTRO
DE INGENIERÍA GENÉTICA
Y BIOTECNOLOGÍA

Ave. 31, e/ 158 y 190, Playa, Habana, Cuba
Tel: (537) 7271 6022
www.cigb.edu.cu



LinkedIn: CIGBCuba



Twitter: CIGBCuba



Facebook: CIGBCubaCuba

Proctokinasa®

RECOMBINANT STREPTOKINASE
SUPPOSITORY FOR THE
TREATMENT OF ACUTE
HEMORRHOIDAL CRISIS

Suppository

ón rectal/ Rectal administration

EXCLUSIVO
AL USE ON

positorios/
positories

rio contiene

ory contain

a recombin

Streptokina

omercial

so csp/ H

er Biotec

abana,

Heber
Biotec
Heber Biotec, S.A.
La Habana, Cuba

Heber
Biotec
Heber Biotec, S.A.
La Habana, Cuba

Heber
Biotec
Heber Biotec, S.A.
La Habana, Cuba

Proctokinasa
Estreptoquinasa recombinante
Recombinant streptokinase
Supositorio/ Suppository

Proctokinasa
Estreptoquinasa recombinante
Recombinant streptokinase
Supositorio/ Suppository

Proctokinasa
Estreptoquinasa recombinante
Recombinant streptokinase
Supositorio/ Suppository

Proctokinasa
Estreptoquinasa recombinante
Recombinant streptokinase
Supositorio/ Suppository

QUICK AND
EFFECTIVE SOLUTION

QUICK AND EFFECTIVE SOLUTION

- NON-INVASIVE TREATMENT.
- QUICK AND EFFECTIVE THERAPEUTIC RESPONSE.
- IN A FEW DAYS THE INFLAMMATION, PERIANAL PAIN AND RECTAL BLEEDING DISAPPEAR.
- ELIMINATES THROMBI AND MICROTHROMBI FROM THE INFLAMMATORY PROCESS.
- REDUCES SURGICAL AND INVASIVE PROCEDURES SUCH AS THROMBECTOMY.
- IMPROVES THE QUALITY OF LIFE OF THE PATIENT.
- QUICK RETURN TO DAILY ACTIVITIES.

PHARMACEUTICAL FORM

Suppository

STRENGTH

Recombinant streptokinase 200,000 IU 2 g

PRESENTATION

- Heat-sealable pre-formed socket blister containing 4 suppositories of 200,000 IU of recombinant streptokinase
- Case containing a PVC/LDPE blister for 4 suppositories
- Case containing an aluminum/LDPE blister for 4 suppositories

COMPOSITION

Each suppository (2 g) contains 200,000 IU recombinant streptokinase; thiomersal 20 µg.

PERIOD OF VALIDITY AND STORAGE CONDITIONS

Stable for 24 months at 2 to 8 °C. Do not freeze.

INDICATIONS

Proctokinasa® is indicated for people over 18 years of age, with a clinical diagnosis of acute hemorrhoidal disease (fluxion [crisis] or hemorrhoidal thrombosis), generally characterized by sudden onset perianal pain, with tumors of variable size and appearance, which may be red- violaceous, associated with anal edema, rectal bleeding, itching, mass sensation, constipation, among other signs and symptoms.

CONTRAINDICATIONS

Hypersensitivity to the product (streptokinase) or to any of the components of the formulation (thiomersal, salicylates, including aspirin).

PRECAUTIONS

- Streptococcal infection (including rheumatism), active internal bleeding (< 3 weeks), or other conditions where there is a high risk of bleeding.
- Infection difficult to treat due to its location (recent prescription of anticoagulants, menorrhagia and menstrual period, hemorrhagic diathesis, erosive ulcer lesions of the digestive tract, recent major surgery (less than 14 days).
- No studies have been conducted on the application of **Proctokinasa®** in children under 18 years of age, neither during pregnancy, nor during breastfeeding. Its use is not recommended in these populations.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

It should only be used under MEDICAL PRESCRIPTION. Contains thiomersal: may cause allergic reactions.

UNDESIRABLE EFFECTS

Proctokinasa® is safe and tolerable. The main adverse effects reported after use are not causally related to the product. They are related to the clinical manifestations