SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DISTREPTAZA
Streptokinase + Streptodornase
15000 IU + 1250 IU
rectal suppositories

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository (2 g) contains 15000 IU of streptokinase (*Streptokinasum*) and 1250 IU of streptodornase (*Streptodornasum*).

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

2 g rectal suppositories

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Supportive treatment of pelvic inflammatory disease (PID) – inflammatory diseases of the ovaries, fallopian tubes and endometrium.
- Adhesions after abdominal surgical procedures.
- Acute haemorrhoidal disease and chronic haemorrhoidal disease.
- As a supportive treatment in perirectal abscesses and fistulas with extensive inflammatory infiltration.

4.2 Posology and method of administration

Dosage

Adults
Dosage depends on the type and severity of the inflammatory state.
Use according to doctor's prescription.

In serious conditions, the following quantities are administered respectively:
3 x 1 suppository for first 3 days
2 x 1 suppository for next 3 days
1 x 1 suppository for next 3 days
in less serious conditions:
2 x 1 suppository for 3 days
1 x 1 suppository for next 4 days
or
2 x 1 suppository for 2 days.

Average number of suppositories used in therapy is 8-18.
Average course of treatment is 7-10 days.

Children and adolescents
The safety of Distreptaza in children and adolescents has not established.

Elderly population
There is no information of dosage adjustment in patients over 65 years old.

Hepatic impairment
Distreptaza is administered as rectal suppositories. It is not metabolised in liver, no dosage adjustment is necessary in patients with hepatic impairment.

Renal impairment
There is no information of dosage adjustment in patients with renal impairment.

Method of administration
After removing from a blister, the suppository should be inserted deep into the rectum.

4.3 Contraindications

The medicinal product should not be used:
- in case of hypersensitivity to the active substance or to any of the excipients listed in section 6.1;
- if a patient has wounds covered with a fresh scab or surgical sutures in the area of application: the product should not come into contact with wounds covered with fresh scab or surgical sutures, as this may lead to suture loosening and consequential bleeding;
- after haemorrhage for about 10 days, as it may cause rebleeding;
- with medicinal products containing calcium salts;
- in acute connective tissue inflammation without symptoms of suppuration;
- in patients with reduced blood clotting;
- with anticoagulants due to the risk of local bleeding.

4.4 Special warnings and precautions for use

The product may cause local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

The medicinal product Distreptaza should not be used with anticoagulants due to the risk of local bleeding.

4.6 Fertility, pregnancy and lactation

Pregnancy
Distreptaza should not be used during pregnancy.

Breastfeeding
Distreptaza should not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

Distreptaza has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Rare (≥1/10,000 to <1/1,000):
General disorders and administration site conditions: allergic conditions, hyperthermia and bleeding diathesis, local pain and swelling.

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 the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products: Al. Jerozolimskie 181C, 02-222 Warsaw, tel.: +48 22 49-21-301, fax: +48 22 49-21-309, e-mail: https://smz2.ezdrowie@gov.pl
You can also report side effects to the Marketing Authorisation Holder.

4.9 Overdose

There are no known symptoms of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Streptokinase, complex medicines, ATC code: B06AA55

5.2 Pharmacokinetic properties

Distreptaza in a suppository dosage form contains two active substances: streptokinase and streptodornase.
Streptokinase is the activator of plasminogen, a proenzyme present in human blood, which under the influence of streptokinase converts into plasmin demonstrating the ability to dissolve human blood clots.
Streptodornase is an enzyme displaying the ability to dissolve viscous nucleoprotein mass, dead cells or pus, not affecting live cells and their physiological functions.
Distreptaza in the form of suppositories is used alone or as a supplementary medicinal product, which activity enables much better access of antibiotics or chemotherapeutics to the focus of inflammation.
The product reduces the subjective ailments and considerably shortens the course of treatment.

5.3 Preclinical safety data

Studies on laboratory animals (guinea pigs and white mice) have revealed no toxic effect of Distreptaza.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
Hard fat

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze.

6.5 Nature and contents of container

6 pcs - 1 blister pack containing 6 pcs
10 pcs - 2 blister packs, each containing 5 pcs
PVC/PE blister pack in a cardboard box.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

R/0211

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 August 1967
Date of latest renewal: 09 May 2013

10. DATE OF REVISION OF THE TEXT

10/2023