Package leaflet: Information for the patient

DISTREPTAZA
Streptokinase + Streptodornase
15000 IU + 1250 IU
Rectal suppositories

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Disteptaza is and what it is used for

Distreptaza is a drug in the form of rectal suppositories, contains active substances streptokinase and streptodornase.
Disteptaza causes liquefaction of blood clots and morphotic components of pus, thanks to which antibiotics, chemotherapeutics and antibodies easy reach sources of infection.
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 an supportive treatment in perirectal abscesses and fistulas with extensive inflammatory infiltration.

2. What you need to know before you use Distreptaza

Do not use Distreptaza:
- if you are allergic to active substances or any of the other ingredients of this medicine (listed in section 6),
- if you have wounds covered with a fresh scab or surgical sutures in the area of application,
- after haemorrhage for about 10 days, as it may cause rebleeding,
- with other medicinal products containing calcium salts,
- in acute connective tissue inflammation without symptoms of suppuration,
- if you have reduced blood clotting,
- with anticoagulants due to the risk of local bleeding.

Warnings and precautions
Talk to your doctor or pharmacist before using Distreptaza.
The drug should not come into contact with wound covered with fresh scab or surgical sutures, as it may lead to suture loosening and secondary bleeding from the wound. The product may cause local irritation.

Other medicines and Distreptaza
Tell your doctor if you are taking, have recently taken or might take any other medicines.
One should not use simultaneously Distreptaza and anticoagulant drugs, because local bleedings may occur. The product should not be used with other medicinal products containing calcium salts.

Pregnancy and breast-feeding
The drug can not be used by women in pregnant or during breast-feeding.

Driving and using machines
The drug does not have any impact on driving or machinery service.

3. How to use Distreptaza

Always use this medicine exactly as your doctor has told you.
Check with your doctor if you are not sure.
After removing from a blister, the suppository should be inserted deep into the rectum.

The recommended dose

Adults
Dosage depends on the type and severity of the inflammatory state.
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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
In general it is good tolerated.
Sometimes can occur: allergic reactions, higher body temperature, tendency to bleedings, local pain and swelling.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:
Al. Jerozolimskie 181C, 02-222 Warsaw, tel.: 22 49-21-301, fax: 22 49-21-309, e-mail: https://smz.ezdrowie@gov.pl.
You can also report side effects to the Marketing Authorisation Holder. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Distreptaza

Store in a refrigerator (2°C – 8°C). Do not freeze.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

LOT on the packaging indicates the lot number.
EXP on the packaging indicates the expiry date.

6. Contents of the pack and other information

What Distreptaza contains
- The active substances are: streptokinase and streptodornase
- The other excipients are: liquid paraffin, hard fat

What Distreptaza looks like and contents of the pack

What Distreptaza looks like
The drug has the form of a suppository of a white-cream color in the shape of a cone or cylinder with a pointed end.

Contents of the pack
1 blister of 6 pieces
2 blisters of 5 pieces
PVC/PE blister pack in a cardboard box.

Marketing Authorisation Holder and Manufacturer
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