

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed
without a doctor's prescription

Procto-Glyvenol® Suppositories Procto-Glyvenol® Cream

Composition:

The active ingredients and their quantity:

Suppositories: Each suppository contains:

Tribenoside 400 mg

Lidocaine 40 mg

Cream: Each 100 g contains:

Tribenoside 5%

Lidocaine HCl 2.12%

* Inactive and allergenic ingredients in the
preparation – see section 6.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise
information about the medicine. If you have further
questions, refer to the doctor or pharmacist.
The medicine is intended for use in adults
only. Use it in the correct manner. Consult the
pharmacist if you need further information. Refer
to the doctor if symptoms of the illness worsen
or if they do not improve after seven days or if
you feel that the effect of the preparation is too
weak or too strong.

1. What is the medicine intended for?

Procto-Glyvenol suppositories are intended for
the local relief of hemorrhoids. Procto-Glyvenol
cream is intended for relief of internal and
external hemorrhoids.

Therapeutic group:

Tribenoside: Reduces the permeability of the
blood vessels and possesses an inhibitory
effect on a series of substances which play a
significant role in the inflammatory process and
the occurrence of pain.

Lidocaine: A local anesthetic, relieves pain and
itching.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active
ingredients or to any of the additional
ingredients contained in the medicine.

Special warnings regarding use of the medicine

Before beginning treatment with Procto- Glyvenol, tell the doctor if:

- You suffer from liver disease
- There is loss of blood, when blood is suspected
in the fecal matter, when there are anal pains
and high fever. When these problems persist for
longer than a week, if the problems get worse
or when unusual and new symptoms arise

- You are suffering from another medical
condition
- You suffer from allergies
- You are already taking other medical products
either internally or externally (including non-
prescription preparations).

After initial appearance of the problems, self-
medication should not be continued for longer
than a week. Repeated use should only occur
after a conclusive medical diagnosis has been
made and should not last longer than a week at
a time. For a diagnosis, consult a doctor.

Should any hypersensitive reactions occur, stop
the treatment immediately and consult with the
doctor.

**If you are taking, or have recently taken,
other medicines, including non-prescription
medicines or nutritional supplements, tell the
doctor or pharmacist.**

Pregnancy and breastfeeding:

Do not use Procto-Glyvenol during pregnancy,
especially not during the first three months of
pregnancy, unless explicitly prescribed by a
doctor.

Do not use Procto-Glyvenol while breastfeeding,
unless explicitly prescribed by a doctor. In such
a case, stop breastfeeding.

Use of the medicine in children

The medicine is not intended for use in children.
There is no clinical experience with use in
children.

Important information about some of the ingredients of the medicine

Procto-Glyvenol cream contains cetyl alcohol,
which may lead to local skin reactions (e.g.,
contact dermatitis). The cream also contains
methyl and propyl parahydroxybenzoate.
These substances may trigger allergic reactions
(possibly delayed).

3. How should you use the medicine?

Check with the doctor or pharmacist if you are
uncertain.

The usual dose is generally:

Suppositories: insert one suppository morning
and evening.

Cream: apply the cream morning and evening.
Following improvement in your condition, reduce
the dosage to once a day.

If there is no improvement in your condition
within 7 days, refer to the doctor.

- **Do not exceed the recommended dose.**
- Do not swallow. For external use only.
- Be careful that the cream or suppositories do
not come into contact with the eyes.

Method of administration:

Suppositories:

First, wash your hands thoroughly. Remove the
wrapper from the suppository and wet it with some
water. Lie on your side. Insert the suppository as
deep as you can into the rectum using a finger.
If the suppository is too soft for insertion, cool
it in the refrigerator for 30 minutes or pour cold
water on it before opening the wrapper. Wash your
hands after inserting the suppository.

Cream:

For external use: Thoroughly clean and dry the
rectal area. Use a small amount of the cream,
apply it gently to the area.

For internal use: if the doctor asked you to
insert the medicine into the rectum: first, attach
the screw-on plastic applicator to the tip of
the open tube. Insert the tip of the applicator
into the rectum and gently squeeze the tube to
insert the cream. Remove the applicator from the
tube and wash it with hot water and soap. When
finished, close the tube with the cap.

Wash your hands after using the medicine.

• If you accidentally took a higher dosage:

There is no experience with overdosage. If
you took an overdose, or if you or a child
has accidentally swallowed the medicine,
refer immediately to a doctor or proceed to
a hospital emergency room, and bring the
package of the medicine with you.

- If you forgot to use the medicine at the required
time, skip the forgotten dose and use the next
dose at the scheduled time. Do not take two
doses together.

How can you contribute to the success of the treatment?

If you suffer from hemorrhoids, avoid eating
highly-spiced foods and opt for a diet which
promotes the formation of soft stools (a light,
vegetable-based diet). Sufficient intake of liquids
and physical activity will also assist. You should
avoid putting on weight and deal with excess
weight. Furthermore, ensure good anal hygiene.
These measures will help you to reinforce the
effects of Procto-Glyvenol.

Do not take medicines in the dark! Check the
label and the dose each time you take medicine.
Wear glasses if you need them. If you have
further questions regarding use of the medicine,
consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Procto-Glyvenol
may cause side effects in some users.

Do not be alarmed when reading the list of side
effects. You may not suffer from any of them.

Some side effects occur very rarely (in less than
1 in 10,000 patients).

In very rare cases, severe allergic reactions
(anaphylactic reactions) may occur after the
use of Procto-Glyvenol.

**Discontinue treatment with Procto-Glyvenol
and seek immediate medical attention if you
notice any of the following signs; it could be an
allergic reaction:**

- difficulty breathing or swallowing;
- swelling of the face, lips, tongue and/or throat
area;
- severe skin itching with a red rash and/or
bumps on the skin;
- irregular heartbeat.

Some side effects occur rarely (in 1 to 10 in
10,000 patients). Procto-Glyvenol is normally
tolerated well. However, in rare cases, skin

reactions, such as burning, itching or redness,
may occur. These reactions may occur in the
treated area or nearby.

If a side effect occurs, if one of the side effects
worsens or if you suffer from a side effect
not mentioned in this leaflet, consult with the
doctor.

Side effects can be reported to the Ministry
of Health by clicking on the link "Report Side
Effects of Drug Treatment" found on the Ministry
of Health homepage (www.health.gov.il) that
directs you to the online form for reporting side
effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other
medicine, must be kept in a safe place out of
the sight and reach of children and/or infants
in order to avoid poisoning. Do not induce
vomiting, unless explicitly instructed to do so
by the doctor.
- Do not use the medicine after the expiry date
(exp. date) that appears on the package.
The expiry date refers to the last day of that
month.
- **Storage:** Store below 25°C.

6. Additional information

In addition to the active ingredients, the
medicine also contains:

Suppositories:

Hard fat #2 (Witepsol W35), Hard fat #1
(Witepsol E85)

Cream:

Purified water, Liquid paraffin, Stearic acid,
Sorbitol liquid (non crystallizing), Cetyl alcohol,
Macrogol cetostearyl ether (Cetomacrogol-
1000), Isopropyl palmitate, Sorbitan stearate
(Arlacel-60), Methylparahydroxybenzoate,
Propylparahydroxybenzoate.

What the medicine looks like and the contents
of the package:

Appearance: Suppositories: Colored yellowish-
white and torpedo-shaped.

Cream: Colored white and
homogenous

Package: Suppositories: A package containing
10 suppositories

Cream: A package containing a 30-
gram tube and a screw-on applicator

Registration holder and address: GlaxoSmithKline
(Israel) Ltd., Basel Street 25, Petach Tikva
Manufacturer and address: Novartis Consumer
Health SA, Nyon, Switzerland

This leaflet was checked and approved by the
Ministry of Health in May 2017.

• Registration number of the medicine in the
National Drug Registry of the Ministry of
Health:

Suppositories: 067-40-23920-00

Cream: 044-65-23919-00

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