



# Venoplant

## Procto gel

### INDICATIONS

Venoplant Proctogel is a medical device that acts by protecting the rectal mucosa and perianal area in case of irritation, creating an optimal environment for repair processes while also protecting the area from external physical agents (rubbing) and bacteria. It has been developed to provide relief from the symptoms (pain, burning sensation and itching) associated with anorectal disorders such as haemorrhoids, and anal and perianal fissures.

The mechanism by which the medical device acts is based on the ability to promote a film-forming effect by the polymeric and polysaccharide component on the injured area, thus providing relief, also thanks to the moisturising action exerted by the glycerine and the polymeric and polysaccharide component itself. Its slightly acidic pH formulation respects the particular nature and balance of the areas to be treated.

**Composition:** Isocide IMU, Glycerine, Carbopol, xanthan gum, Centella asiatica dry extract, Melilotus dry extract, Propylene glycol, Sodium hydroxide 30%, sodium methylparaben, Disodium EDTA, Glicacyd ECO, Olive milk, Resassol, Zanthalene 20%, Lactic acid, water.

### Posology and how to use it

The device is intended for both non-invasive use (anal and perianal application) and invasive use in relation to body orifices (endorectal application) by means of the appropriate applicator.

For anal and perianal applications, thoroughly cleanse the area to be treated before applying the product. Spread the product on the area to be treated 3 to 4 times a day.

For endorectal application:

- a) Unscrew the cap, break the bottom of the safety seal with the back cap and screw the intra-rectal cannula with protective cap onto the tube neck.
- b) Remove the cap and squeeze until the cannula is filled, releasing a small amount of product to lubricate the cannula.
- c) Gently insert the cannula into the rectum.
- d) Squeeze the tube again until enough product is introduced.
- e) After use, thoroughly clean the cannula and cover it with the cap.

The treatment duration depends on the evolution of symptoms. The treatment should not last more than 30 days.

### Warnings

- For rectal use only.
- Keep out of the reach of children.
- In case of concomitant drug treatments, consult the doctor.
- No studies have been conducted in pregnancy and lactation. Therefore, in these cases, use the product only after consulting a doctor.
- Product functionality is guaranteed if the primary packaging is intact. Do not to use the device if the packaging is damaged or not fully intact when first opened.
- Do not use it after the expiry date specified on the package.
- Do not let it come into contact with the eyes. In case of accidental contact, thorough washing with warm water is recommended.
- Do not dispose the tube as household waste after use.

## Interactions

No interactions related to the use of the Venoplast Proctogel medical device are known to date.

## Contraindications

Venoplast Proctogel has no specific contraindications. Do not use the product in case of known hypersensitivity or incompatibility with even one single component of the formulation.

## Side effects

To date, no side effects related to the correct use of the product have been detected. Discontinue use and consult a doctor in case of irritation of the rectal mucosa or perianal area.

It is important to tell your doctor or pharmacist if you notice any side effects that are not described in this information leaflet.

## Minimum storage life

24 months.










Validity after first opening: 1 month.

## Storage

Store in a cool, dry place, away from heat sources, at a controlled temperature not above 25°C. The expiry date applies if product is properly stored and its package is not damaged. Do not dispose of the product or its package as household waste after use.

Rev.01/2021

Net quantity: Sale: 30 g e

| <i>Symbols used on the package</i>                                                  |                     |                                                                                     |                                                 |                                                                                       |                                                                         |
|-------------------------------------------------------------------------------------|---------------------|-------------------------------------------------------------------------------------|-------------------------------------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|  | <i>Manufacturer</i> |  | <i>Do not use if package is damaged</i>         |  | <i>Medical device in compliance with Directive 93/42/EEC as amended</i> |
|  | <i>Batch code</i>   |  | <i>Consult instructions for use, before use</i> |  | <i>Caution</i>                                                          |
|  | <i>Use-by date</i>  |  | <i>Non-sterile medical device</i>               |  | <i>Store at temperatures not above 25°C</i>                             |



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REF 912915307286