

Revaree®

(HYALURONIC ACID SODIUM SALT 0.25%)

Vaginal suppositories
For intravaginal use only

PRODUCT DESCRIPTION

REVAREE vaginal suppositories are semi-solid, off-white suppositories for intravaginal administration. Each 2 g vaginal suppository contains 5 mg of hyaluronic acid sodium salt in a base consisting of a mixture of semi-synthetic glycerides. REVAREE vaginal suppositories carry out their activity thanks to the presence of hyaluronic acid, a mucopolysaccharide which is abundantly distributed in many body tissues. Hyaluronic acid has the capacity of retaining water thereby forming a moist environment that is supportive of hydration and lubrication.

INDICATIONS

REVAREE is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

INSTRUCTIONS FOR USE

Place the suppository into the vagina, preferably at bedtime.

The frequency with which the product should be used depends on the grade of the vaginal dryness. One vaginal suppository every two or three days for a period of thirty days is suggested, unless otherwise recommended by a health care provider. Avoid excessive handling of the vaginal suppository; it is designed to melt at body temperature.

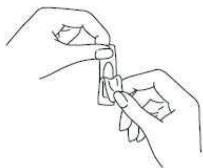


Figure 1

1. Remove the vaginal suppository from its packaging by pulling on the two pre-cut flyers of the plastic strip (as shown in Figure 1).
2. Holding the suppository with your thumb and a finger, insert it into the vagina.
3. Using your finger, gently push the suppository into the vagina as far as it will comfortably go. This should be done while lying on your back with your knees bent.
4. Once inside the vagina, the suppository melts. Lie down as soon as possible. This will keep leakage to a minimum.

INGREDIENTS

Hyaluronic acid sodium salt 5 mg, semi-synthetic glycerides.

CONTRAINDICATIONS

The administration of the product is contraindicated in any patient with a known or suspected hypersensitivity to any of its ingredients.

PRECAUTIONS

There are no studies of REVAREE vaginal suppositories in pregnant and breastfeeding women. Therefore, in such circumstances, the safety of use of the product has not been established and it is necessary to consult a doctor.

WARNINGS

- Use of all products for topical use, especially if prolonged, may cause sensitisation. If this occurs, stop treatment and consult the doctor to start suitable therapy.
- If your condition worsens, consult a doctor immediately.
- Keep the product out of the reach of children.
- Avoid contact with eyes.
- Do not swallow.
- The expiry date is stated both on the pack and on the plastic strip and it refers to the product in an unopened and correctly stored pack. Do not use after the date stated on the pack, or if the pack is opened or damaged.
- Do not use with condoms.
- This is not a spermicide and does not provide protection against pregnancy.

INTERACTIONS

Interactions with other products are not known, therefore it is advisable to consult a doctor before using REVAREE vaginal suppositories in association with other medical devices, drugs or other products for vaginal use.

ADVERSE REACTIONS

All suspected adverse reactions occurring during the use of REVAREE vaginal suppositories should be reported to a doctor.

HOW SUPPLIED

REVAREE is available as suppositories for vaginal use. Each pack contains 10 single-use vaginal suppositories of 2 g.

STORAGE

Store the product tightly closed, away from light and heat, preferably at a temperature between 4 °C (39°F) and 25 °C (77°F). Avoid heat over 30°C (86°F).

NOT MADE WITH HORMONES

NOT MADE WITH PARABENS

MANUFACTURED BY:

FARMA-DERMA s.r.l.

Via dell'Artigiano 6-8 - 40010 Sala Bolognese (BO) - ITALY

DISTRIBUTED BY:

BONAFIDE HEALTH, LLC.

500 Mamaroneck Avenue, Suite 510, Harrison NY, 10528

DATE OF REVISION

2024/02

DRA5470021524