

SANTES®

VAGINAL PESSARIES

COMPOSITION

Each 2 g vaginal pessary contains: hyaluronic acid sodium salt 5.00 mg, tocopheryl acetate 1.00 mg, retinyl palmitate 1.00 mg, semi-synthetic glycerides q.s.

CATEGORY

Single-use Medical Device.

PROPERTIES

SANTES® vaginal pessaries is a preparation containing hyaluronic acid, the main component of the ground substance of the dermis. Used locally, hyaluronic acid protects and improves the elasticity of the vaginal mucosa, while creating the best possible conditions for the migration and proliferation of the cells responsible for the repair process. Thanks to its hygroscopic properties, hyaluronic acid forms a protective barrier from the external environment, promoting the tissue regeneration process. SANTES® vaginal pessaries contains low-molecular-weight hyaluronic acid that allows high bioavailability and efficiency, accelerating the wound healing and repair mechanisms of the vaginal mucosa. In addition, the combination of retinyl palmitate (vitamin A) and tocopheryl acetate (vitamin E) ensures antioxidant action against free radicals, protecting the vaginal environment.

PACKAGE

14 vaginal pessaries of 2 g each.



CLINICAL INFORMATION

INDICATIONS

Treatment and prevention of vaginal disorders, including injuries, ectopia (known as folds) and other changes in the vaginal mucosa, including those caused by physical treatments (DTC, laser therapy, cryotherapy, radiotherapy) in adult women. Soothing and lubricating treatment, especially in post-menopausal patients.

CONTRA-INDICATIONS

Known hypersensitivity to the components.

SIDE-EFFECTS

No side-effects have been reported to date. Tell your doctor or pharmacist about any undesirable effects you suspect may have been caused by using the product.

INCOMPATIBILITIES/INTERACTIONS

To date, there are no known interactions with other devices, substances or medicinal products.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES

No effects on the ability to drive and use machines have been reported.

METHOD OF ADMINISTRATION

1. Wash your hands thoroughly before opening the package. **2.** Remove a single

blister from the blister strip, taking care not to damage the remaining blisters. **3.** Remove the pessary from the blister. **4.** Gently slide the pessary into the vagina, trying to insert it as far as it will go to prevent accidental product leakage.

DOSAGE

One pessary at night for 14 consecutive days. The treatment may be repeated as necessary. For vaginal disorders caused by physical treatments, administer the product from the first day of treatment.



WARNINGS

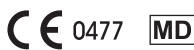
The use of any product for topical use, especially if prolonged, can lead to sensitisation; if this occurs, discontinue treatment and speak to your doctor to start suitable therapy. Discontinue treatment the day before undergoing any specific gynaecological tests or treatments. The product should be administered vaginally only. No injuries from overdose have been reported under normal conditions of use. Use during pregnancy must be evaluated by medical consultation. Do not use the product if you are allergic to any of the components. Do not use the product after the expiry date shown on the package. Do not use the product if the box and/or blister are not intact. Keep out of reach of children. Do not swallow. Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority of the Member State in which you are established.

SPECIAL PRECAUTIONS FOR STORAGE

Store at room temperature ($\leq 25^{\circ}\text{C}$), protected from light, in a cool place.

DISPOSAL

There are no special requirements to be followed for disposal of the product. Check local regulations in force.



Leaflet paper PAP 22

Recycling - Please check the regulations in your municipality



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