

BIGUANELLE[®] PESSARIES

VAGINAL PESSARIES

COMPOSITION

Each 2 g vaginal pessary contains: Aloe barbadensis oil extr. 60 mg, colloidal silica 30 mg, lactic acid 1 mg, potassium chloride 4 mg, disodium edetate 3 mg, PHMB hydrochloride 15

CATEGORY

Single-use Medical Device

PROPERTIES

BIGUANELLE[®] Pessaries consist of a base of semi-synthetic glyceride which breaks down rapidly in the vagina, facilitating the release of the components. The product is preserved with polyhexanide (PHMB), a cationic surfactant well tolerated in the mucosa. BIGUANELLE[®] Pessaries helps restore, and subsequently maintains, natural vaginal pH and physiological conditions, it lubricates the vaginal mucosa and aids the re-epithelialization processes.

CLINICAL INFORMATION

INDICATIONS

BIGUANELLE[®] Pessaries is indicated for the treatment and prevention of vaginal disorders in adult women and is also an adjuvant treatment for HPV (Human Papilloma Virus) infection. It restores and maintains the natural physiological conditions of the vaginal environment, promoting re-epithelialisation after surgical treatment of lesions caused by the papilloma virus.

CONTRAINDICATIONS

Known hypersensitivity to the components.

SIDE EFFECTS

In some cases, intolerance (burning or irritation) may occur. However, this does not have any consequences and does not require any changes to the treatment. 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 10 consecutive days. The treatment may be repeated as necessary.



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. Do not use the product if you are allergic to any of the components. Use during pregnancy must be evaluated by medical consultation. Do not use the product if you are allergic to any of the components, after the expiry date or if the box is 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.

PRECAUTIONS FOR STORAGE

Store between 0 and 25°C, protected from light and in a cool place.

PACKAGE

10 vaginal pessaries, 2 g each

DISPOSAL

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

