

Biguanelle®

Isotonic Gynaecological Solution, pH 4.0

COMPOSITION

Hydroxyethyl cellulose	0.60 g
Lactic acid	0.20 g
Glycerol	2.00 g
Potassium chloride	0.15 g
Sodium edetate	0.10 g
Polyhexamethylene biguanide hydrochloride (PHMB)	0.10 g
Purified water	q.b. a 100 ml

CATEGORY

Single-use Medical Device.

PROPERTIES

The use of BIGUANELLE® helps restore natural physiological functions, even during traumatic pharmacological or physical treatments. The use of BIGUANELLE® during the treatment of vaginal disorders or after physical treatment helps restore normal vaginal physiology. The product is preserved with polyhexanide (PHMB), a cationic surfactant well tolerated by all mucosae.

PHARMACEUTICAL FORM

Solution in 100 ml bottle.

CLINICAL INFORMATION

INDICATIONS

Treatment of vulvovaginitis and cervicovaginitis of any origin and nature by restoring and maintaining the natural physiology of the vaginal environment. Adjuvant in re-epithelialisation processes following physical treatment (diathermocoagulation, laser therapy, cryotherapy), exerting a protective, barrier effect in adult women.

CONTRA-INDICATIONS

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 affects 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.

DOSAGE AND METHOD OF ADMINISTRATION

One single application is sufficient and can be repeated, if necessary, after 4 days as advised by a doctor.

INSTRUCTIONS FOR USE



1 Remove the sealed cap by pushing it to the side;



2 Remove the cannula from the protective packaging and insert it in the bottle, making sure it is securely positioned;

- 3** Choose a suitable position which will allow the solution to stay inside the vagina when taking effect;
- 4** Carefully insert half the cannula into the vaginal canal;
- 5** Squeeze the bottle until it is completely empty. Allow the liquid to remain in the vagina for a few minutes so the solution can take effect. You should also follow any instructions given by your treating doctor.



WARNINGS

Use only once and discard the single-dose container with any residual content. The use of any product for topical use, especially if prolonged, can lead to sensitisation; speak to your doctor if this occurs. 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, 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 at room temperature ($\leq 25^{\circ}\text{C}$), protected from light and in a cool place.

PACKAGE

One 100 ml bottle with vaginal cannula.

Manufacturer INGE S.p.A. Via Garibaldi 190, 20024 S. Maria Rossa di Garbagnate Milanese (Milan, Italy)

DISPOSAL

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

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