# Biguanelle® Gel

Dermatological gel, pH 4.0

**COMPOSITION**

| | |
|---|---|
| Hydroxyethyl cellulose | 2.50 g |
| Glycerol | 2.00 g |
| Potassium chloride | 0.20 g |
| Polyhexamethylene biguanide hydrochloride (PHMB) | 0.15 g |
| Sodium edetate | 0.15 g |
| Lactic acid | 0.01 g |
| Purified water | q.s. to 100 ml |

**CATEGORY**
Multidose medical device.

**PROPERTIES**
Biguanelle® gel protects the skin and mucosa in affected areas, allowing them to follow their physiological evolution, even in the presence of injured skin. The product is preserved with polyhexanide (PHMB), does not contain any perfume and is stabilized at pH 4.0.

**PHARMACEUTICAL FORM**
Dermatological gel.

## CLINICAL INFORMATION

**INDICATIONS**
Biguanelle® gel is beneficial in the adult population in all cases of vulvitis and balanitis, as it limits the proliferation of pathogenic species and restores the physiological pH of treated areas. Biguanelle® gel exerts a barrier effect that protects from the risk of secondary infections, thus promoting the healing process and restoration of physiological conditions. It can be applied to mucosa and skin, even in the presence of lesions.

**CONTRA-INDICATIONS**
Known hypersensitivity to the components.

**SIDE-EFFECTS**
Rare cases of intolerance are possible (burning, irritation or redness) due to the presence of the contact allergen PHMB. Tell your doctor and pharmacist about any undesirable effects you suspect may have been caused by using the product and discontinue treatment.

**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**
Unless prescribed otherwise by your doctor, apply the gel on the area to be treated, massaging lightly, once or twice a day (morning and evening) for at least 7 days.

**WARNINGS**
Close immediately after use. 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. 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 the product at room temperature (≤ 25 °C), protected from light and in a cool place.

**PACKAGE**
30 ml tube

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

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Recycling - Please check the regulations in your municipality

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