

# XYMINAL®

Vaginal pessaries of MYO-INOSITOL at pH 6

## COMPOSITION

Each 1 g vaginal pessary contains: myo-inositol 2.00 mg; semi-synthetic glycerides 998.00 mg.

## CATEGORY

Single-use Medical Device.

## PACKAGE

3 vaginal pessaries of 1 g each.



## CLINICAL INFORMATION

### THE PROCESS OF CONCEPTION

The characteristics of the seminal fluid and cervical-vaginal ecosystem are among the determining factors of the fertilisation process. In particular, the stage of the menstrual cycle, evaluation of cervical mucus, basal temperature and the use of electronic hormone sensing devices are the indicators used to identify a woman's most fertile days. Cervical mucus appears at the start of the fertile stage of the menstrual cycle (between days 9 and 11 of the cycle). The mucus changes in appearance, becoming increasingly abundant, fluid and viscous, culminating at the ovulatory peak (days 13 to 15), before gradually reducing. During the ovulatory peak, the presence of fluid, clear and abundant cervical mucus helps the spermatozoa reach the oocyte. In these conditions, the seminal fluid is better protected from vaginal acidity: the relatively alkaline pH of the cervical mucus protects the semen while preserving sperm vitality.

### PROPERTIES

The product is a preparation containing myo-inositol, whose local use creates optimal conditions for oocyte fertilisation. Myo-inositol helps increase the fluidity of the cervical mucus and seminal fluid, facilitating the migration of the spermatozoa towards the oocyte. With its antioxidant properties, myo-inositol protects the spermatozoa from the action of reactive oxygen species (ROS) naturally present in the vaginal environment. The composition of XYMINAL® generates an optimal pH for sperm vitality, balancing out the vaginal acidity responsible for sperm inactivation.

### INDICAZIONI

XYMINAL® XYMINAL® increases the chances of fertilisation and pregnancy in spontaneous or induced cycles, by helping create vaginal conditions favourable to sperm function. Therefore, the use of XYMINAL® in adult women, associated with careful planning of sex, helps couples to conceive.

### 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 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 or use machines have been reported.

#### **DOSAGE AND METHOD OF ADMINISTRATION**

Wash your hands carefully before opening the package. Gently insert 1 pessary into the vagina every other day (preferably in the evening before going to bed), during the periovulatory phase (from day 11 to day 16 in a regular 28-day cycle), which can be identified using electronic hormone sensing devices and/or direct evaluation of the cervical mucus. Schedule sex after a minimum of 6 hours from insertion of the pessary.

#### **OVERDOSE**

No overdose symptoms have been reported to date.



#### **WARNINGS**

The use of any product for topical use, especially if prolonged, can lead to sensitisation. The product should be administered vaginally only. Do not use the product if you are allergic to any of its components. Do not use the product after the expiry date. 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, dry place.

#### **DISPOSAL**

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

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