ÆSCULAPIUS
FARMACEUTICI

SUMMARY OF PRODUCT CHARACTERISTICS

1.- TRADE NAME OF THE MEDICINAL PRODUCT

GINENORM 0,1% VAGINAL SOLUTION
GINENORM 1 g POWDER FOR VAGINAL SOLUTION

2.- QUALITATIVE AND QUANTITATIVE COMPOSITION

0.1% Vaginal solution
100 ml contain:
- Ibuprofen isobutanolammonium g 0.1
  equal to Ibuprofen g 0.0698

1 g Powder for vaginal solution
One sachet of 1 g contains:
- Ibuprofen isobutanolammonium g 1
  equal to Ibuprofen g 0.698

Excipients: 2- phenoxyethanol-p- methyl /-ethyl /-propyl /-butyl hydroxybenzoates, propylene glycol.

For the complete list of excipients, see paragraph 6.1

3.- PHARMACEUTICAL FORM

0.1% Vaginal solution - 5 bottles of ml 100
1 g Powder for vaginal solution - 10 sachets

4.- CLINICAL PARTICULARS

4.1.- Therapeutic indications

Vulvovaginitis and cervicovaginitis of all origin and types.
Pre and post operative treatment in gynaecological surgery.
Use the ready prepared solution in relation to the intensity of the phlogosis as prescribed.

4.2.- Posology and method of administration

1 or 2 vaginal irrigations per day, according to medical opinion, using the bottle containing the solution ready to use or dissolving the content of 1-2 sachets in 1 liter of water for each vaginal irrigation.

4.3.- Contraindications

Hypersensibility to the active substance or to any of the excipients.
The use of product is not foreseen in pediatric age, unless the doctor considers it absolutely necessary.
Contraindicated in pregnancy and lactation (see Pregnancy and lactation).

4.4.- Special warnings and precautions for use

Serious skin reactions, some of which lethal, including esfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been very rarely reported in association with the use of NSAIDs (see 4.8). In the early phases of therapy the patients seem to be exposed to higher risk: the rising of the reaction appear in most cases within the first month of treatment. Ginenorm has to be interrupted at the early appearing of skin rash, mucosa lesions or any other sign of hypersensitivity.
The topical use of products, especially if prolonged, can lead to hypersensiblity phenomena.
In this case, it is necessary to interrupt the therapy and begin a suitable therapy.
The product must not be used in cases of serious vulvovaginitis, specific or aspecific.
The product contains, among the excipients, para-hydroxybenzoates as preservatives that may cause allergic reactions (possibly delayed) and propylene glycol that may cause skin irritation.
The solution can be used at room temperature or warm, placing the bottle under a flow of hot water.
1. Remove the guarantee and closing seal pushing sideways.
2. Extract the sterile cannula from its protective wrapping, fit it to the bottle and make sure it is stable.
3. Apply so that the solution can perform its cleansing and therapeutic action.
4. Gently insert the cannula into the vagina and compress the bottle until completely emptied.
5. Keep the liquid in the vagina for a few minutes to permit the solution to perform its therapeutic action. Follow any other advise from the doctor.

4.5.- Interactions with other medicines or other forms of interaction
No studies of interaction have been performed.

4.6.- Pregnancy and lactation
Contraindicated during pregnancy and lactation.

4.7.- Effects on the ability to drive and use machines
Ginenorm does not interfere with the ability to drive a vehicle or use machines.

4.8.- Undesirables effects
Bubble reactions including Stevens-Johnson syndrome and Toxic Epidermal Necrolysis (very rarely).
Skin and subcutaneous tissue disorders: drug reaction with eosinophilia and systemic symptoms (DRESS) (unknown frequency).

4.9.- Overdose
In cases of severe poisoning, metabolic acidosis may occur.

5.- PHARMACOLOGICAL PROPERTIES

5.1.- Pharmacodynamics properties
Pharmacotherapeutic group:
Non Steroid, anti-inflammation product for vaginal administration. ATC Code G02CC01.

5.2.- Pharmacokinetic properties
Bioavailability studies have established that topical use of the medicine does not give rise to plasmatic effects of any clinical and/or toxicological importance. The plasmatic levels of the medicine are very low and at the limit of analytic sensitivity.

5.3.- Preclinical safety data

The pre-clinical data reveal absence of risk for humans on the base of conventional studies of safety pharmacology, toxicity after repeated administration, genotoxicity, cancerogenic potential, reproductive toxicity.

6.- PHARMACEUTICALS PARTICULARS

6.1.- List of excipients

0.1% Vaginal solution :
2- Phenoxyethanol-p- methyl /-ethyl /-propyl /-butyl hydroxybenzoates, Polysorbate 20, Propylene glycol, Flower essence, Deionized water.

1 g Powder for vaginal solution :
Imidazolidinylurea, sodium chloride.

6.2.- Incompatibilities

Not pertinent.

6.3.- Shelf life

0.1% vaginal solution:
3 years

1 g powder for vaginal solution:
5 years

6.4.- Special precautions for use

No special preacutions for storage.

6.5.- Nature and contents of container

0.1% Vaginal solution:
Low density, polythene bottle containing a clear, ready-to-use solution.

1 g Powder for vaginal solution:
Heat-sealed sachets made of laminated paper-polyethylene-aluminum-polyethylene containing flowing white or slightly yellow and odorless powder

6.6.- Special precautions for disposal and other handling

No special precaution

7.- MARKETING AUTHORIZATION HOLDER

AESCULAPIUS FARMACEUTICI S.r.l. - Via Cefalonia, 70 - 25124 BRESCIA (Italy)

8.- MARKETING AUTHORIZATION NUMBERS

0.1% Vaginal solution – 3 bottles: M.A.. n° 029135023
0.1% Vaginal solution – 5 bottles: M.A.. n° 029135023
1 g Powder for vaginal solution: A.I.C. n° 029135011

9.- DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of MA renewal: October 2012

10.- DATE OF REVISION OF THE TEXT
December 2018