

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aci-Jel Therapeutic Vaginal Jelly

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The gel contains 0.9386 % w/w Glacial Acetic Acid in a buffered formulation (as described in the application).

For excipients, see section 6.1

3 PHARMACEUTICAL FORM

Vaginal gel.

White mobile gel of characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To restore and maintain vaginal acidity, to reduce recurrence and severity of trichomonas infection or in the management of non-specific vaginitis or cervicitis.

4.2 Posology and method of administration

Route of Administration

Vaginal use

Recommended Dose

One applicatorful intravaginally once or twice daily for up to 2 weeks or as prescribed.

4.3 Contraindications

None known.

4.4 Special warnings and special precautions for use

If there is no improvement or the condition is aggravated, consult the doctor.

Do not use in conjunction with barrier methods of contraception.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

For glacial acetic acid no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely, local irritation and inflammation.

4.9 Overdose

Aci-Jel Therapeutic Vaginal Jelly is intended for intravaginal use. If accidental ingestion occurs, an appropriate method of gastric emptying may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aci-Jel Therapeutic Vaginal Jelly helps restore vaginal pH. Acetic acid is also bactericidal or bacteriostatic to many types of organism.

5.2 Pharmacokinetic properties

There have been no pharmacokinetic studies of absorption of the excipients used in Aci-Jel Vaginal Jelly. It is unlikely that there is any systemic absorption of any of the ingredients of the product.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin
Castor oil
Propyl hydroxybenzoate
Tragacanth
Acacia
Egg albumin impalpable powder
Perfume lavender compound 13091
Potassium hydroxide pellets
Potassium bitartrate
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Epoxy resin lined, blind end aluminium tubes with polyethylene caps.
Each tube contains 85g of jelly. A plastic vaginal applicator is supplied with each pack.

6.6 Instructions for use and handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Janssen-Cilag Limited
Saunderton
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HP14 4HJ
UK.

8 MARKETING AUTHORISATION NUMBER

PA 748/19/1

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