

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0748/017/003

Case No: 2066954

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Janssen-Cilag Ltd

50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Gyno-Pevaryl 150 mg Vaginal Pessaries

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **09/03/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gyno-Pevaryl 150 mg Vaginal Pessaries

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pessary contains 150 mg Econazole Nitrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pessary

The pessaries are white to off white and torpedo shaped.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of fungal or yeast infections of the vagina and vulva.

4.2 Posology and method of administration

For vaginal use.

One pessary to be inserted deep into the vagina daily for three consecutive days.

4.3 Contraindications

Hypersensitivity to any imidazole preparation or other vaginal antifungal products.

4.4 Special warnings and precautions for use

1. This preparation is not for oral use.
2. Gyno-Pevaryl should only be used by those women who have symptoms of candidosis.
3. If they believe or suspect that they might have a sexually transmitted disease, either as well as, or instead of, candidosis, they should consult their own doctor.
4. The preparation should not be used if they are pregnant, or think that they might be pregnant, without first consulting a doctor.
5. It should not be used by those under 16 years of age or over 60 years without first consulting a doctor.
6. The woman should see her doctor if, after treatment:
 - There is not complete relief of symptoms within 7 days.
 - There is the recurrence of symptoms within 4 weeks of treatment.
 - She has more than one episode of infection within a 6 month period, even if they completely resolve with treatment.
 - Adverse effects such as redness, irritation or swelling associated with the treatment occur.

7. Self medication should not be undertaken if the woman has:

- Any abnormal or irregular vaginal bleeding.
- Any blood staining of a vaginal discharge.
- Any vulval or vaginal sores, ulcers or blisters.
- Any associated lower abdominal pain or dysuria.

In all of these cases, she should consult her doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Contact between contraceptive diaphragms or condoms and this product must be avoided since the rubber may be damaged by this preparation.

Although not studied, based on the chemical similarity of econazole with other imidazole compounds, a theoretical potential for competitive interaction with compounds metabolised by CYP3A4/2C9 exists. Due to the limited systemic availability after vaginal application (see 5.2 Pharmacokinetic Properties), clinically relevant interactions are unlikely to occur. In patients on oral anticoagulants, such as warfarin and acenocoumarol, caution should be exercised and monitoring of the anticoagulant effect should be considered.

4.6 Pregnancy and lactation

In animals, econazole nitrate has shown no teratogenic effects, but is foetotoxic at high doses. The significance of this in man is unknown, as there is no evidence of an increased risk when taken in human pregnancy. However, as with other imidazoles, econazole should be used in pregnancy only if the practitioner considers it to be necessary.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The most frequently reported adverse events in clinical trials were application site reactions, such as burning and stinging sensations, pruritus, and erythema.

Based on post-marketing experience, the following adverse reactions have also been reported:

Skin and subcutaneous tissue disorders; general disorders and administration site conditions.

Very rare (<1/10,000): Localised application site (mucocutaneous) reactions, such as erythema, rash, burning and pruritus. Isolated reports of localised allergic reactions. Isolated reports of generalised allergic reactions, including angioedema and urticaria.

Hypersensitivity has rarely been recorded; if it should occur, administration should be discontinued.

4.9 Overdose

This product is intended for vaginal use and by that route overdose is extremely unlikely. If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered desirable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: (Antiinfectives and antiseptics, excl. combinations with corticosteroids, imidazole derivatives)

ATC CODE: G01A F05

Econazole nitrate has no anti-inflammatory action, no effects on the circulation, no central or autonomic nervous effects, no effects on respiration, no effect on α or β adrenergic receptors, no anticholinergic or antiserotonic reactions.

A broad spectrum of antimycotic activity has been demonstrated against dermatophytes, yeasts and moulds. A clinically relevant action against Gram positive bacteria has also been found.

Econazole acts by damaging cell membranes. The permeability of the fungal cell is increased. Sub-cellular membranes in the cytoplasm are damaged. The site of action is most probably the unsaturated fatty acid acyl moiety of membrane phospholipids.

5.2 Pharmacokinetic properties

Econazole nitrate is poorly absorbed from the vagina and skin. No active drug has been detected in the serum, but radio labelling has shown that absorption is less than 0.1%. When administered orally, peak serum levels occur two hours after dosing. About 90% of the absorbed dose is bound to plasma proteins. Metabolism is limited, but primarily occurs in the liver. Metabolites are excreted in the urine. Five major and two minor metabolites have been identified.

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

Hard fat (Wecobee M)

Hard fat (Wecobee FS)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

Store in the original container.

6.5 Nature and contents of container

Available in PVC/PE strips containing three pessaries.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Janssen-Cilag Ltd
50-100 Holmers Farm Way
High Wycombe
Bucks
HP12 4EG
UK

8 MARKETING AUTHORISATION NUMBER

PA 0748/017/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 January 1978

Date of last renewal: 12 January 2008

10 DATE OF REVISION OF THE TEXT

March 2010