SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Zalain 300mg vaginal suppository

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each ovule contains 300mg of Sertaconazole, nitrate.
For excipients, please see 6.1.

3. PHARMACEUTICAL FORM

Ovule for vaginal use. White ovule with torpedo shape

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
Zalain 300mg ovule is indicated for local treatment of vaginal infections caused by fungi of the genus Candida.
In the absence of clinical symptoms, single medical examination showing the presence of Candida yeasts on the vaginal mucosa cannot be the basis for initial treatment.

4.2 Posology and method of administration
A ovule should be incerted into the vagina at bedtime, preferably lying down.
If there are clinical symptoms, a second ovule should be applied in 7 days.

4.3. Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4. Special warnings and precautions for use
Not recommended for use with soap acidic pH (acidic pH favors the multiplication of fungi).
It is not recommended to use a contraceptive diaphragms or condoms during treatment of Zalain ovule, since there is risk of them tearing.
It is not recommended the concomitant use of spermicides. Any local vaginal therapy can disable local contraception.

4.5. Interaction with other medicinal products and other forms of interaction
There is no evidence of interaction of sertaconazole nitrate with other medicines.

4.6. Fertility, Pregnancy and lactation

Fertility
No data

Pregnancy
Studies conducted in animals have shown no teratogenic effects. Therefore there is no reason to expect malformations in humans. Up to date, no clinical evidence of any defects or foetotoxic effect of sertaconazole nitrate used during pregnancy. Because of formulation and administration (single dose) and the absence of systemic absorption, use of Zalain ovule during pregnancy is possible only on medical advice and if the benefits outweigh any possible risk.

Lactation
There is no evidence of passing sertaconazole nitrate in breast milk.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Undesirable effects
Frequencies are defined by MeDRA convention as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to< 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data).

General disorders and administration site conditions:
- manifestations of local intolerance (burning sensation or vaginal pruritus)
- possible allergic reactions

4.9. Overdosage
Overdosage impossible because of concentration and route of administration. In case of accidental overdose by mouth, a symptomatic treatment should be apply.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Gynaecologic anti-infective and anti-septic drugs.
A.T.C Code: G01AF: Imidazole derivatives.
Mechanism of action:
The mechanism of action is similar to that of all compounds from the same class, and it relies on the inhibition of the ergosterol synthesis.

Pharmacodynamic effects:
Sertaconazole is a new local imidazole product and have broad-spectrum effect on pathogenic dimorphic fungi (Candida Albicans, C.tropicalis, C. Spp, Pityrosporum orbiculare), dermatophytes (Trychophyton, Epidermophyton and Microsporum) and other Gram-positive microbes (Staphylococcus, Streptococcus) causing infections in the skin or mucous membranes.

Clinical efficacy and safety :
Therapeutic efficacy and safety of Sertaconazole nitrate at patients with vaginal Candida was studied and compared in several clinical trials for the most commonly used azole antifungal drugs.
In all studies Sertaconazole nitrate showed rapid and sustained action and a high rate of complete cure of the participating patients.

Paediatric population: No data

5.2. Pharmacokinetic properties
Absorption: After single administration of an ovule in vaginal fluid and after the seventh day.
In three studies it was found no systemic absorption of sertaconazole nitrate in plasma in both healthy volunteers and patients with confirmed vaginal candidiasis.
It should be noted that in one of the studies, it was used particularly low quantitative threshold detection by HPLC - 2,5 ng / ml.
Distribution: Not applicable
Biotransformation: Not applicable
Elimination: Not applicable
Linearity / non-linearity: Not applicable
Pharmacokinetic-pharmacodynamic relationship: In essence, the efficiency depends on the time during which maintain a minimum inhibitory concentration for the pathogen.

5.3. Pre-clinical safety data
Long-term toxicity studies show that Sertaconazole has a low toxicity in animals, being similar

to that of other imidazole antifungal drugs. A comparison of the plasma from rats tested in those studies with the quantification limit - never reached in humans – led to the conclusion that Sertaconazole has a large safety margin.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Solid hemi-synthetic glycerides (Witepsol H19)
Solid hemi-synthetic glycerides (Suppocire NAI 50)
Silicon, colloidal, anhydrous.

6.2. Incompatibilities
This medicine must not be used with spermicides.

6.3. Shelf-life
5 years.

6.4. Special precautions for storage
Keep below 30ºC.

6.5. Nature and contents of container
Carton box with one ovule in thermo PVC/PE.

7. MARKETING AUTHORISATION HOLDER

Ferrer Internacional, S.A.
Gran Vía Carlos III, 94
08028 Barcelona (Spain)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST MARKETING AUTHORISATION

10. DATE OF TEXT REVIEW