EU PSUR Work Sharing
Summary Assessment Report
Econazole Nitrate and Econazole Nitrate with Triamcinolone acetonide
HU/H/PSUR/0016/002

Invented name of the medicinal product(s)
GYNO-PEVARYL 150 mg vaginal suppository
PEVARYL 1% cream
PEVARYL G vaginal suppository

INN (or common name) of the active substance(s)
Econazole nitrate and econazole nitrate with triamcinolone acetonide

MAHs whose PSURs were included in this work-sharing
Janssen-Cilag: GYNO-PEVARYL 150 mg vaginal suppository, PEVARYL 1% cream
Johnson & Johnson: PEVARYL G vaginal suppository

Pharmaco-therapeutic group (ATC Code)
G01AF05

Indications authorised in the P-RMS for the product
Econazole (econazole nitrate and base) for topical use is indicated for treatment of cutaneous candidiasis, dermatophytosis, and pityriasis versicolor.
Econazole nitrate for gynaecologic use is indicated for the treatment of vulvovaginal mycoses and mycotic balanitis.
Econazole nitrate/triamcinolone acetonide is indicated for treatment of skin infections by dermatophytes or Candida spp., in which inflammatory symptoms are prominent

Pharmaceutical form(s) and strength(s)
Suppositories: 150 mg econazole nitrate in 1 suppository
Cream: 8.583 mg econazole (10.0 mg econazole nitrate in 1 g cream)

PSUR Period
The period covered by this work sharing assessment was 16.11.2009 to 15.11.2012.

Final Conclusion
Based upon the safety data received within the period of this PSUR, no major areas of safety concerns are identified. No new safety concerns or change in benefits have been identified in the PSUR assessment.
The benefit-risk profile has been well documented for greater than 30 years. Econazole and econazole nitrate/triamcinolone acetonide continue to be effective in the treatment of cutaneous and gynaecological fungal infections.

In the light of the information provided in the reviewed PSUR, the P-RMS/ CMDh considers there were no new major findings affecting the overall safety profile of econazole nitrate / econazole nitrate with triamcinolone acetonide and the benefit-risk profile of the medicinal products remains favourable.

Recommendations:

- **Amendments to the Product Information**

During the assessment of the information in the PSUR the following issues were considered:
  - With regard to the self-administration of the suppositories in pregnant women the addition of a wording is necessary stating that women should thoroughly wash their hands prior to application because ascending infections are the main reason for pre-term deliveries.
  - If the cream is used simultaneously with latex containing condoms or diaphragms the contraceptive efficacy of these latex-containing condoms or diaphragms may be impaired, hence, the cream should not be used simultaneously. In addition, women using spermicide contraceptives should consult their physician since the administration of the cream may inactivate the spermicide.

It has been agreed that the following amendments to the Product Information are required:

- **SmPC wording**

**Section 4.2 Posology and Method of Administration**

*Pregnant women should thoroughly wash their hands before self-administering GYNO-PEVARYL suppositories (see section 4.6 Pregnancy and Lactation for further recommendations). In addition, with regard to GYNO-PEVARYL Cream it is recommended that administration should take place without the use of the applicator, or should be performed by the physician.*

**Section 4.4 Special Warnings & Special Precautions**

*The concurrent use of latex condoms or diaphragms with vaginal anti-infective preparations may decrease the effectiveness of rubber contraceptive agents. Therefore, products such as GYNO-PEVARYL Cream should not be used concurrently with a diaphragm or latex condom. Patients using spermicidal contraceptives should consult their physician since any local vaginal treatment may inactivate the spermicidal contraceptive (see section 4.5 Interactions).*

**Section 4.5 Interactions**

*Contact should be avoided between latex products such as contraceptive diaphragms or condoms and GYNO-PEVARYL Cream since the constituents of GYNO-PEVARYL Cream may damage the latex. Patients using spermicidal contraceptives should consult their physician since any local vaginal treatment may inactivate the spermicidal contraceptive (see section 4.4 Special Warnings & Special Precautions).*
• Agreed topics for close monitoring in the next PSUR:
No specific issues are proposed for close monitoring and review in the next PSUR.