Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gyno-Pevaryl Once 150 mg Vaginal Pessary

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 pessary is light beige and torpedo-shaped

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of vaginitis due to *Candida albicans* and other yeasts.

4.2 Posology and method of administration

For vaginal use.

One pessary to be inserted deep into the vagina.
In pregnant women, it is recommended that administration takes place without the use of the applicator, or is performed by a physician. Pregnant women should thoroughly wash their hands before self-administering Gyno-Pevaryl Once 150mg vaginal pessaries.

4.3 Contraindications

Hypersensitivity to any imidazole preparation other vaginal antifungal products or to any other ingredient of Gyno-Pevaryl Once 150mg vaginal pessaries.

4.4 Special warnings and precautions for use

For intravaginal use only.

This preparation is not for oral use.

Gyno-Pevaryl should be used only by those women who have symptoms of
candidosis.

If they believe or suspect that they might have some other sexually transmitted disease, either as well as, or instead of, candidosis, they should consult their own doctor.

The preparation should not be used if they are pregnant, or think that they might be pregnant, without first consulting a doctor.

It should not be used by those under 16 years of age or over 60 years without first consulting a doctor.

The woman should see her doctor if, after treatment:
- There is not complete relief of symptoms within 7 days.
- There is 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.

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.

Gyno-Pevaryl vaginal pessaries should not be used in conjunction with other internal or external treatment of the genitalia.

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

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

Patients using spermicidal contraceptives should consult their physician since any local vaginal treatment may inactivate the spermicidal contraceptive (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interactions

Econazole is a known inhibitor of CYP3A4. Due to the limited systemic availability after vaginal application (see Section 5.2. Pharmacokinetic Properties), clinically relevant interactions are unlikely to occur but have been reported with oral anticoagulants. In patients taking oral anticoagulants, such as warfarin or acenocoumarol, caution should be exercised and the anticoagulant effect should be monitored more frequently.

Adjustment of the oral anticoagulant dosage may be necessary during and after the treatment with econazole.

Contact between latex products such as contraceptive diaphragms or condoms and this product must be avoided since the constituents of the product 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).

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies have shown reproductive toxicity (see section 5.3).

Because there is vaginal absorption, as with other imidazoles, econazole should be used in pregnancy only if the practitioner considers it to be necessary.

Breast-feeding
Following oral administration of econazole nitrate to lactating rats, econazole and/or metabolites were excreted in milk and were found in nursing pups. It is not known whether econazole nitrate is excreted in human milk. Caution should be exercised when using Gyno-Pevaryl 1 vaginal pessary if the patient is breast-feeding.

Fertility
Results of econazole animal reproduction studies showed no effects on fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The safety of Gyno-Pevaryl Vaginal Cream and Vaginal Pessaries was evaluated in 3630 patients who participated in 32 clinical trials.

Based on pooled safety data from these clinical trials, the most commonly reported adverse reactions were (with % incidence) pruritus (1.2%) and skin burning sensation (1.2%).

Including the above mentioned adverse reactions, the following table displays adverse reactions that have been reported with the use of Gyno-Pevaryl Vaginal Cream and Vaginal Pessaries from either clinical trial or postmarketing experiences. The displayed frequency categories use the following convention:

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); and not known (cannot be estimated from the available clinical trial data).

Adverse Reactions

System Organ Class	**Adverse Reactions**			
	Frequency Category			
	Common (≥1/100 to <1/10)	**Uncommon** (≥1/1,000 to <1/100)	**Rare** (≥1/10,000 to <1/1,000)	**Not known**
Immune System Disorders				Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Pruritus, Skin Burning sensation	Rash	Erythema	Angioedema, Urticaria, Contact dermatitis, Skin exfoliation
Reproductive System and Breast Disorders		Vulvovaginal burning sensation		
General Disorders and Administration Site Conditions				Application site pain, Application site irritation, Application site swelling

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Adverse events associated with overdose or misuse of Gyno-Pevaryl Once 150mg vaginal pessaries is expected to be consistent with adverse drug reactions already listed in Section 4.8. (Undesirable effects).In the event of accidental ingestion, nausea, vomiting and diarrhoea may occur. If necessary treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC CODE: G01A F05

Econazole is an imidazole derivative. The compound acts by damaging the membranes of bacterial and fungal cells. Both the cellular and subcellular membranes are affected. Econazole apparently disturbs the permeability characteristics of the membrane which allow leakage of potassium and sodium ions and other intra cellular components. Macro-molecular synthesis may also be inhibited. Econazole is active against dermatophytes, yeast, moulds and Gram-positive bacteria. Gram-negative bacteria are generally resistant to econazole.

5.2 Pharmacokinetic properties

Econazole nitrate is poorly absorbed after vaginal application. Using radiolabelled techniques, it has been determined that between 2.5% and 7% of vaginally applied econazole nitrate is absorbed. However, no antimycotic activity could be detected in the serum after vaginal application of 5 g of 1% econazole nitrate cream or a suppository containing 50 mg econazole nitrate.

5.3 Preclinical safety data

Low neonatal survival and fetal toxicity was associated only with maternal toxicity. In animal studies, econazole nitrate has shown no teratogenic effects but was fetotoxic in rodents at maternal subcutaneous doses of 20 mg/kg/day and at maternal oral doses of 10 mg/kg/day. The significance of this in humans is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polygel
Colloidal anhydrous silica
Hard fat (Witepsol H19; Wecobee FS)
Stearyl heptanoate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Multi-plast strip containing one pessary per pack (polyvinylacetate copolymer film laminated to a low density polyethylene) and a PVC/PE moulded applicator designed to contain one pessary.

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

It is important to use this medicine at the right times and in the right way.

Insert one pessary high in the vagina, using the Ortho pessary applicator, in the evening before going to bed:

1. Tear open the foil beginning at the V shaped notch and carefully remove the pessary.
2. Withdraw the plunger of the white plastic applicator until it sticks. Push Gyno-Pevaryl Once 150 mg Vaginal Pessary gently into the cup. Do not force the pessary into the cup as it may be difficult to expel, particularly if it has begun to soften.
3. Whilst laying down, knees bent and spread apart, gently insert the applicator, pessary first, well into the vagina. Press the plunger to deposit the pessary and then remove the applicator.

The applicator is no longer required so it can be disposed of safely.

7 MARKETING AUTHORISATION HOLDER

KARO PHARMA AB
Box 16184
103 24 Stockholm
Sweden

8 MARKETING AUTHORISATION NUMBER

PA22650/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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