

PRODUCT INFORMATION FOR MEDICAL PROFESSIONALS

1. TRADE NAME OF THE PRODUCT

Regelle Vaginal Moisturising Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

6.5 g tube containing Purified Water; Ph Eur, 78.82 % m/m.

For further composition details see section 6.1.

3. PHYSICAL PROPERTIES

Regelle is a soft white vaginal gel.

4. CLINICAL PARTICULARS

4.1 Medical Applications

Regelle is a vaginal gel intended for the symptomatic relief of vaginal atrophy, dryness, itching, irritation & discomfort.

Regelle is not intended for use as a substitute for Hormone Replacement Therapy (HRT), but it is a non-hormonal alternative where oestrogen therapy is not indicated. It may be given concomitantly with HRT for the symptomatic relief of vaginal atrophy.

Multiple applications of the gel result in a change of pH towards the normal physiological range of premenopausal women.

Regelle is designed to bind to the vaginal epithelial cells and maintain hydration, leading to an improvement in vaginal fluid volume, moisture and elasticity without changing vaginal mucosal cytology.

4.2 Posology and Method of Administration

Posology

Adults:

Intravaginal application.

The contents of one applicator to be inserted into the vagina every three days, preferably in the morning.

Depending on the level of dryness, Regelle can be used more or less frequently and can be used daily.

Children:

Do not use in children.

Method of Administration

Shake the contents down to the narrow end of the tube. Break and remove the cap and insert the entire neck of the tube into the vagina as far as it will go while lying down on your back with knees bent or in a sitting position. Squeeze out the contents by maintaining constant pressure and then withdraw the tube. Discard the tube appropriately.

4.3 **Contraindications**

Known allergy to any of the constituents.

4.4 **Special Warnings and Special Precautions for Use**

If irritation persists or develops, consult a Healthcare Professional.

Regelle contains no spermicide and will not protect against pregnancy.

4.5 **Interaction with Medicaments and other forms of Interaction.**

None known.

4.6 **Pregnancy and Lactation**

Consult your Healthcare Professional before use.

4.7 **Effects on ability to Drive and Use Machines**

None.

4.8 **Undesirable effects**

Leakage of the gel or an infrequent white residue.

4.9 **Overdose**

Regelle is non-toxic and overdosing is not anticipated as each dose is applied through an individual applicator.

5. **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**

Regelle acts to moisturise the vaginal epithelium. Polycarbophil in Regelle attaches to mucin in the vaginal cavity and to the vaginal epithelium to enable Regelle to provide moisturisation. Polycarbophil can incorporate about sixty times its weight in water and provides a moist film over the vaginal wall hydrating the underlying mucosa.

5.2 **Pharmacokinetic Properties**

Regelle contains purified water to moisten the vaginal epithelium. Pharmacokinetic studies are not considered necessary.

5.3 **Preclinical Safety Data**

Studies on a purified water based vaginal moisturiser showed it to have no dermal or vaginal irritancy effects in Rabbits and to be non-allergenic in Guinea-Pigs. Minimal ocular irritation was observed in Rabbits. Chronic toxicity, mutagenicity, carcinogenicity and reproduction studies were not undertaken.

6. **PRODUCT PARTICULARS**

6.1 **List of other Constituents**

Polycarbophil, mineral oil, glycerol, hydrogenated palm oil glyceride, carbomer 974 P, and sorbic acid.

6.2 **Incompatibilities**

None known. Regelle can be used with condoms.

6.3 **Shelf Life**

24 months.

6.4 **Special Precautions for Storage**

Do not store above 25°C. Store in a dry place. Do not refrigerate or freeze. Keep out of reach of children.

6.5 **Nature and Contents of Container**

A white, single use applicator made of low density polyethylene (LDPE) with a break-off cap and. Each applicator contains 6.5 g of gel and will deliver 2.5 g of gel. Each applicator is packed in cardboard cartons that come in three different sizes each containing 3, 6 or 12 applicators respectively.

6.6 **Instructions for Use/Handling**

Not applicable.

7. **NAME AND ADDRESS OF PRINCIPAL**

Kora Corporation Ltd (trading as Kora Healthcare),
Swords Business Park,
Swords,
Co. Dublin,
IRELAND.

8. **CLASSIFICATION**

Medical Device Class IIb device under Annex IX, rule 5 Medical Devices Directives 93/42/EEC.

9. **DATE OF (PARTIAL) REVISION OF THE TEXT**

July 2013