

REGELLE

The Long Lasting Non-Hormonal Solution to Vaginal Dryness and Atrophy

ONE APPLICATION LASTS THREE DAYS

HORMONE FREE suitable with:

- Cancer treatments (including breast cancer)
- Systemic HRT

DUAL ACTION and LONG LASTING

- Immediate comfort and relief from symptoms
- Moisturising for up to 3 days

RESTORES AND REJUVENATES

- Delivers purified water where it is needed, clinically proven to help:
 - rehydrate tissue^v
 - return elasticity and natural secretions^{vi,vii}
 - restore the natural pH^{viii}

COST EFFECTIVE FLEXIBLE DOSING

- The most cost effective long lasting vaginal moisturiser
- Regelle is up to 28% lower in price when compared to other long lasting vaginal moisturisers*.
 - Single use pre-filled applicators in 3 pack sizes:
 - 3 pack, 6 pack, 12 pack (up to 9, 18 and 36 days' supply respectively)

READILY AVAILABLE

- Available on NHS prescription
 - 3 pack £3.29, 6 pack £5.41, 12 pack £8.32
- Available over the counter
 - 3 pack £5.91, 6 pack £9.74, 12 pack £14.97

PIP CODES: 3 pack 381-6469, 6 pack 381-6477, 12 pack 381-6485

Regelle is a class IIb medical device



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Abbreviated Prescribing Information

Name of Product: Regelle Vaginal Moisturising Gel. **Presentation:** Regelle is a soft white vaginal gel in a single use intravaginal tube. **Indications:** Regelle is a vaginal gel intended for the symptomatic relief of vaginal atrophy, dryness, itching, irritation & discomfort. **Dosing and Administration:** 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. **Contra-indications:** Known allergy to any of the constituents. **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. **Interaction with Medicaments and other forms of Interaction:** None known. **Pregnancy and Lactation:** Consult your Healthcare Professional before use. **Undesirable effects:** Leakage of the gel or an infrequent white residue. **Pack Size:** Regelle is available in three different sized packs containing 3, 6 or 12 applicators. **Legal Category:** Medical Device, class IIb. **Name of Principal:** Kora Corporation Ltd (trading as Kora Healthcare), Swords Business Park, Swords, Co. Dublin, Ireland. **Date of Preparation:** 31 July 2013.

i Menopause Matters Survey 2006 and Kora Regelle clinical assessment March 2013.

ii On-line survey conducted between March - April (2009) Results received from 4246 female respondents in Canada, Finland, Sweden, United States of America, and the United Kingdom. Commissioned by Novo Nordisk and conducted by You Gov Zapera.

iii Crandall C, Petersen L, Ganz P, Greendale GA. (2004) Association of breast cancer and its therapy with menopause-related symptoms. *Menopause*, 11(5), 519-530.

iv Sturdee DW, Panay N. (2010) Recommendations for the management of postmenopausal vaginal atrophy. *Climacteric*, 13, 509-522. Early Online, 1-14. Department of Obstetrics & Gynaecology, Heart of England NHS Foundation Trust, Solihull Hospital, Solihull. *Queen Charlotte's & Chelsea Hospital, London, UK.

v Nachtigall LE. (1994) Comparative study: Replens versus local oestrogen in menopausal women. *Fertil Steril*;61, 178-80.

vi Loprinzi CL, Abu-Ghazaleh S, Sloan J, van Haelst-Pisani C, Hammer A, Rowland K, Law M, Windschitl H, Kaur J, and Ellison N. (1997) Phase III randomized double blind study to evaluate the efficacy of a polycarbophil-based vaginal moisturizer in women with breast cancer. *J Clin Oncol.*, 15, 969-73.

vii Bachmann GA, Notalovitz M, Gonzalez SJ, Thompson C, Morecraft BA. (1991) Vaginal dryness in the menopausal woman: clinical characteristics and non hormonal treatment. *Clin Pract Sex.* 7, 1-8.7. M. Gelfand and E. Wendman (1994) Treating vaginal dryness in breast cancer patients: results of applying a polycarbophil moisturizing gel. *Journal of Women's Health*, 3 (6), 427-433.

*Calculated when using the NHS price of 12 pack Regelle v NHS price of other 12 pack equivalent.



Regelle®



Long Lasting NON-Hormonal Vaginal Moisturiser

For Vaginal Dryness and Atrophy

*Approximately 50% of women
experience vaginal drynessⁱ*

Vaginal Dryness and Atrophy

Symptoms of vaginal dryness, atrophy and discomfort are experienced by menopausal and post-menopausal women, however with the right treatment women can successfully relieve these symptoms.

Approximately 50% of Post-Menopausal Women Experience Vaginal Drynessⁱ

- Vaginal dryness will affect approximately 50% of women aged between 51 and 60ⁱ.
- 40% of women who had recently experienced vaginal dryness and pain said it interfered with their sex lifeⁱⁱ.

23-61% of Breast Cancer Survivors Experience Vaginal Atrophyⁱⁱⁱ

- In breast cancer survivors the estimated prevalence of vaginal atrophy ranges from 23% to 61%ⁱⁱⁱ. Prescribing even very low-dose localised oestrogen treatments for these patients can cause concern because of the potential for systemic absorption.

Majority of Patients don't seek Medical Treatment

- Despite the various safe and effective options only 25% seek medical help^{iv}.
- 7 out of 10 patients are too embarrassed to discuss vaginal dryness and pain with their physicianⁱⁱ.

....Yet Treatments Work

The You Gov Zopera 2009 online surveyⁱⁱ found that 67% of those who had or were currently taking treatment experienced improvements, including an improved quality of life, a return to normal sexual activity, and an improvement in the relationship with their partnerⁱⁱ.

Other Causes of Vaginal Dryness and Atrophy

Symptoms of vaginal dryness and atrophy can also affect women during:

- Breastfeeding
- Stress
- Cancer treatment
- Endometriosis treatment
- Fertility treatment
- Other medications: some antihistamines, antibiotics, antidepressants, oral contraceptives, bacterial infection and diabetic treatments

Treatment Options

The menopause is a natural phenomenon which is caused by the gradual decline of oestrogen production. Premature menopause can occur in primary ovarian failure, surgically-induced menopause, radiation-induced menopause and chemotherapy -induced menopause. Oestrogen needs to be supplemented if a woman wishes to avoid suffering adverse conditions that may affect her quality of life.

Oestrogen therapy is not always indicated and non-hormonal alternatives are both sought and preferred.

For many women a NON-hormonal vaginal moisturiser, such as Regelle will be their first choice; especially when HRT or oestrogen treatments are contraindicated, or where use for prolonged periods is cautioned (e.g. those undergoing breast cancer treatments or breast cancer survivors).

Regelle Mode of Action

Regelle is a NON-hormonal bioadhesive gel containing purified water. The gel can incorporate about sixty times its weight in water providing a moist film over the vaginal wall hydrating the underlying mucosa and providing long-lasting relief from the symptoms of vaginal dryness, irritation and painful intercourse.

Regelle provides continuous moisturisation for up to three days after application, unlike short acting lubricants.

Regelle also improves the elasticity of vaginal walls, encourages the return of natural secretions and restores the natural acidity of the vagina.