**DRAFT**

**(INSTRUCTION FOR USE)**

**SanteFem, vaginal suppositories**

**Name.**

SanteFem, vaginal suppositories.

**General characteristics.**

SanteFem suppositories are a vaginal product produced on the basis of hard fat, the main agent being sodium hyaluronate.

Vaginal hyaluronic suppositories help regenerating and healing the genital mucosa, re-epithelizing, restoring physiological pH of the vagina, prevent proliferation of pathogens.

**Composition.** Each suppository contains sodium hyaluronate 8.4 mg, boric acid 600 mg, tea tree oil, rice bran oil, vitamin E, Dragocalm® (oat extract), semi-synthetic glycerides (hard fat).

The total mass of a suppository is 2.0 g.

**Pharmaceutical form.**

Vaginal suppositories.

**Main effect.**

The effect of vaginal suppositories is due to the presence of hyaluronic acid, functioning as structural support, thus ensuring tissue tonicity, nourishing and flexibility. Numerous clinical studies proved the ability of hyaluronic acid to accelerate and improve epithelization and regeneration of tissues.

It is an auxiliary product in treatment of fungal vulvovaginal infections, including recurrent candidal vulvovaginitis. It can be used in combination with systemic antifungal therapy.

*Hyaluronic acid* has a pronounced moisturizing effect, helping to get rid of and to prevent dry mucous membranes.

*Boric acid has* antifungal effect due to binding of the vaginal pathogens in vulvovaginitis, caused by *Candida spp*., both in the acute period and is used for prevention of recurrence, especially in infections in which *non-albicans Candida spp*. are pathogens*.*

*Dragocalm® (oat extract)* has antihistamine effect, which is useful for prevention of allergic reactions caused by fungal infection.

*Rice bran oil* has anti-inflammatory and softening effect, restores moisture content in the vaginal mucosa*.*

*Tea tree oil* has anti-inflammatory, antiseptic, bactericidal and antifungal effects*.*

*Vitamin E* improves regeneration of mucosal epithelium*.*

**Indications for use.**

• To intensify regeneration processes in the areas of atrophic and dystrophic changes of the vaginal mucosa. It is helpful in postnatal rehabilitation, in gynaecological surgeries, in cases of dystrophy due to chemotherapy, ionizing radiation, vaginal dryness caused by oestrogen deficiency.

• Auxiliary remedy in the treatment of vulvovaginal fungal infections in women, including recurrent infections.

• Prevention of recurrences of fungal infections.

• Relieving symptoms of fungal infections – vaginal itch, burning and irritation.

**Special warnings and precautions for use.**

As a rule, the product is well tolerated, in very rare cases allergic reactions are possible. As with other products applied to the skin or mucosae, hypersensitivity reactions, especially in case of prolonged use, are possible. In this case it is recommended to stop using suppositories and to consult a physician for adequate treatment.

Do not exceed recommended dose.

Only for vaginal use. Do not use during menstrual period.

**Contraindications.**

Hypersensitivity to the components of the product. Pregnancy and lactation. Paediatric age.

**Posology and method of administration.**

• Wash your hands with soap and warm water before using suppositories.

• Unwrap the suppository, lie on your back with your knees bent towards your chest and insert the suppository as high as possible into the vagina.

*Vaginal dryness –* 1 suppository 1 time a day (in the evening). The duration of treatment depends on the markedness of discomfort; after the desired effect has been achieved, it is recommended to use suppositories for 2-3 days more.

*Fungal infections* – 1 suppository 1 time a day for 15 days.

*Prevention of recurrent fungal diseases* – 1 suppository 2 times a week for 8 weeks.

Single use product.

**Storage conditions.**

Store in original package at the temperature not exceeding 25 °С. Keep away from children. Do not use suppositories, if the package is damaged or after the expiry date.

**Shelf life.** 2 years from manufacturing date.

**Interaction with other medicinal products.** Not known.

**Package.** 5 or 7 suppositories in a blister, 1 or 2 blisters in a pack.

**Medical device.**

**Manufacturer & Marketing Authorization Holder.**

Joint Stock Company “Lekhim-Kharkiv”.

**Site Address.** Ukraine, 61115, Kharkiv region, Kharkiv, Severyna Pototskoho street, building 36

tel.: +38 (057) 7 147 790, fax: +38 (057) 7 147 791

**lekhim.ua**