VAGI-HEX vaginal tablets

FORMULATION
1 vaginal tablet contains 10.0 mg Hexetidine as an active ingredient. It contains Microcrystalline cellulose, Magnesium stearate, 1-tetradecanol, Sorbitol, Polysorbate 60, Povidone K25, Crospovidone, highly dispersed silicon dioxide, long chain partial glycerides and Tartaric acid as well.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Hexetidine is the active ingredient of Vagi-hex. It is known as 1,3-Bis (ethlyhexil) hexahydro-5 methyl- pyrimidinamine. It has antiseptic activity.

It has been shown that hexetidine has no effect on Lactobacillus which forms physiological vaginal flora.

Hexetidine is a pyrimidine derivate. Because pyrimidine has a similar structure to thiamine, it prevents thiamine pyrophosphate synthesis and further phosphorylation of thiamine, it was suggested that it exerts its activity through disturbing vital functions of pathogenic microorganisms.

Pharmacokinetic properties
Vaginally applied Hexetidine doesn’t have systemic absorption.

INDICATIONS
It is indicated for the treatment of vaginitis as vaginal antiseptic.

CONTRAINDICATIONS
It is contraindicated during the first trimester of pregnancy and in case of hypersensitivity to Hexetidine or any of the ingredients.

WARNINGS/PRECAUTIONS
Vagi-hex may cause local skin reactions in allergic patients. In case allergic reactions occur, the usage of the product should be immediately discontinued.

When used concomitantly with latex products (e.g. vaginal diaphragm or condoms), the vaginal tablet may reduce the protecting effect of these devices.

During the therapy, it is recommended to take special hygienic precautions (e.g. genital hygiene, changing underwear daily) in order get successful treatment.

Usage in pregnancy and lactation
Pregnancy category: B
There are not any controlled studies conducted on pregnant and nursing women. Any product should be avoided in this period. Except the first trimester, administration is only possible after doctor’s decision on the assessment of benefits/risks ratio.
UNDESİRED EFFECTS
In rare cases, vaginal pruritus, burning, redness and pain may occur in vagina. However, these symptoms do not require discontinuation of the product.

An increase in the proliferation of resistant fungus can be observed. Therefore appropriate follow up is necessary. In case of super infections, drug should be discontinued and switched to appropriate treatment.
IN CASE OF AN UNEXPECTED EFFECT, CONSULT YOUR DOCTOR

DRUG INTERACTIONS
All vaginal suppositories and tablets have incompatibility risk when used concomitantly with latex products (e.g. vaginal diaphragm or condoms). Vaginal tablet may reduce the protecting effect of these devices.

DOSAGE AND METHOD OF ADMINISTRATION
Apply twice a day, through a 6 days period. Insert the tablet deeply into the vagina every morning and evening. Even if the complaints (pruritus, discharge) disappear, the therapy should be continued for 6 days. Shorter therapy could cause relapses. The treatment should not be discontinued during the menstruation period.

OVERDOSE
Overdosing by local vaginal application is hardly possible. If couple of tablets simultaneously inserted into dry vagina, the tablets will not dissolve properly. If excess amount of liquid is present in vagina, active substance can discharge out with this liquid.

STORAGE CONDITIONS
Should be stored at 2-8°C in the refrigerator.
Keep it out of reach of children in original package.

PRESENTATIONS AND CONTENT OF CONTAINER
Vagi-hex tablets are presented in a box containing 12 tablets in two blisters, each blister contains 6 tablets.

REGISTRATION HOLDER
ASSOS ilaç, Kimya, Gıda Ürünleri, Üretim, Tic ve San Ltd. Şti.
ÜMRANİYE 34773 İSTANBUL

Producer: On behalf of Drossapharm AG, Switzerland, Artesan, Germany

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