PACKAGE INSERT

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM
LOMEXIN VAGINAL CREAM
LOMEXIN 200 MG VAGINAL OVULES
LOMEXIN 600 MG VAGINAL OVULES

COMPOSITION
LOMEXIN VAGINAL CREAM: Each 5 g contains 100 mg fenticonazole nitrate.

LOMEXIN 200 MG VAGINAL OVULES: Each ovule contains 200 mg fenticonazole nitrate.
Preservatives: Sodium ethyl hydroxybenzoate 0,09 % m/m.
Sodium propyl hydroxybenzoate 0,045 % m/m.

LOMEXIN 600 MG VAGINAL OVULES: Each ovule contains 600 mg fenticonazole nitrate.
Preservatives: Sodium ethyl hydroxybenzoate 0,07 % m/m.
Sodium propyl hydroxybenzoate 0,035 % m/m.

PHARMACOLOGICAL CLASSIFICATION
A 18.6 Vaginal preparations.

PHARMACOLOGICAL ACTION
Pharmacodynamics
Fenticonazole is a potent broad-spectrum antimycotic agent.
The mechanism of action of fenticonazole is thought to be the blocking of oxidant enzymes with accumulation of peroxides and necrosis of the fungal cell; direct action on the membrane.

Pharmacokinetics
The amount of fenticonazole absorbed by the transcutaneous route is negligible.

INDICATIONS
Vulvovaginal candidiasis.

CONTRA-INDICATIONS
LOMEXIN is contra-indicated in patients hypersensitive to imidazoles. Safety in pregnancy and lactation has not been established.
LOMEXIN therapy is not recommended for children.

WARNINGS
When applied to the lesion or at the time of the intravaginal insertion, a slight burning sensation may be felt which disappears rapidly.

The use of topical LOMEXIN, especially if extended, may cause sensitivity to the product. In such case, the treatment should be interrupted and a physician should be consulted to commence an appropriate therapy.

INTERACTIONS
LOMEXIN may damage latex contraceptives and additional contraceptive measures are therefore necessary during local administration.

PREGNANCY AND LACTATION
The use of the product during pregnancy is not recommended. Safety in lactation has not been established.

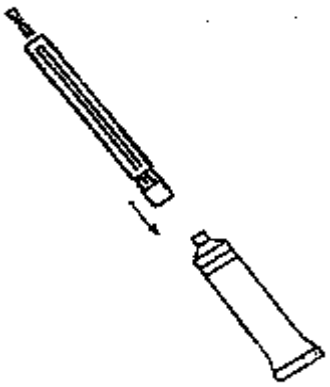
DOSAGE AND DIRECTIONS FOR USE
LOMEXIN VAGINAL CREAM: 5 g should be administered intravaginally every morning and evening for three

days. See “Instructions for use/handling”.

LOMEXIN VAGINAL OVULES: One 200 mg ovule should be administered intravaginally every evening for three days; alternatively, once only administration of a 600 mg ovule should suffice. See “Instructions for use/handling”.

It is advisable that the sexual partner is also treated locally (glans and foreskin) with LOMEXIN CREAM, to prevent re-infection.

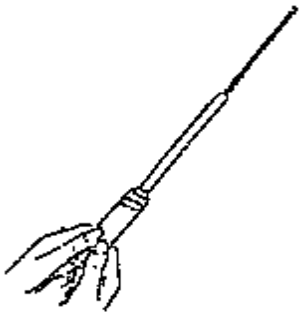
Instructions for use / handling:
LOMEXIN VAGINAL CREAM
Follow the instructions illustrated in the diagram below.
Take care to ensure that the applicator is always perfectly clean. After each use, wash it carefully with warm water and soap.
If the physician advises sterilisation of the applicator, for particular reasons, follow his instructions. Do not, however, use water which is hotter than 50°C, nor organic solvents.
Then dry the applicator and store it in its container.



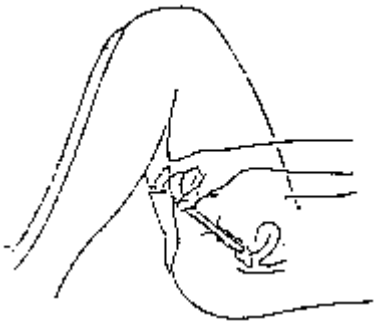
Wash hands thoroughly. Place the open end of the applicator over the opening of the tube of cream.



Squeeze the bottom of the tube gently so that the cream fills the applicator to the top. If there is certain resistance in the piston, pull it gently. Unless otherwise instructed by the physician, the applicator must be completely filled.



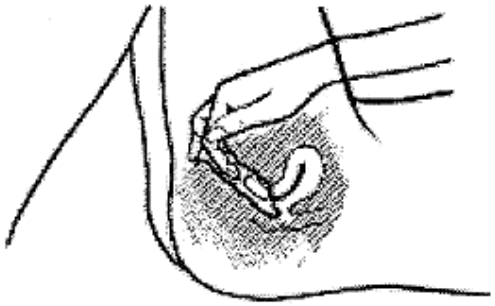
Remove the applicator from the tube, and replace the cap immediately.



In a lying position, with knees raised and spread apart, gently insert the applicator into the vagina as deeply as possible.
Slowly push the piston completely. Remove the applicator from the vagina without touching the piston.

LOMEXIN VAGINAL OVULES
Remove the ovule from the blister pack.

Insert one ovule high into the vagina in the evening before going to bed (this is easiest when lying on your back with your knees bent up). Refer to the diagram.



SIDE-EFFECTS AND SPECIAL PRECAUTIONS
LOMEXIN is generally well tolerated.

General disorders and administration site conditions
Less frequent: Mild and transient erythematous reactions or burning sensations have been reported only exceptionally and normally disappear rapidly.

Allergic reaction may occur less frequently.
In the event of hypersensitivity reactions or the development of resistant microorganisms, treatment should be discontinued.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Following topical application of LOMEXIN, very little fenticonazole is absorbed systemically. Thus overdosage by this route does not occur.
Hypersensitivity reactions should be treated symptomatically and LOMEXIN discontinued.

IDENTIFICATION
LOMEXIN VAGINAL CREAM: A white, homogenous cream intended for intravaginal use.
LOMEXIN VAGINAL OVULES: Oval-shaped, ivory white, opaque, soft gelatine capsules containing a white homogenous oily suspension, intended for intravaginal use. The 200 mg ovule has a mass of approximately 900 mg, and the 600 mg a mass of approximately 1,5 g.

PRESENTATION
LOMEXIN VAGINAL CREAM: Tubes of 30 g supplied with an applicator for vaginal use.
LOMEXIN 200 MG VAGINAL OVULES: Blister packs of 3 ovules.
LOMEXIN 600 MG VAGINAL OVULES: Blister packs of 1 ovule.

STORAGE INSTRUCTIONS
Protect from light. Store below 30°C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS
LOMEXIN VAGINAL CREAM: 29/18.6/0055
LOMEXIN 200 MG VAGINAL OVULES: 29/18.6/0053
LOMEXIN 600 MG VAGINAL OVULES: 29/18.6/0054

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Litha Pharma Pty Ltd
106 16th Rd Midrand

DATE OF PUBLICATION OF THIS PACKAGE INSERT
14 August 2009

LOMEXIN 200 MG VAGINAL OVULES

NAMIBIA
Scheduling status: NS1
Reg. No.: 04/18.6/0131

LOMEXIN 600 MG VAGINAL OVULES

NAMIBIA
Scheduling status: NS1
Reg. No.: 04/18.6/0130

LOMEXIN VAGINAL CREAM

NAMIBIA
Scheduling status: NS1
Reg. No.: 04/18.6/0114