Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Calinda
Vaginal ovules

Each ovule contains:
clindamycin (as phosphate) 100 mg

For a list of inactive ingredients and allergens, see section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

An antibiotic medicine for 3-day treatment of bacterial vaginosis in women.

Therapeutic group: Antibiotic of the lincosamides class.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive to the active ingredient clindamycin, to other antibiotic containing the ingredient lincomycin or to any of the other ingredients in this medicine (see section 6).
- you have previously had inflammation of the colon (colitis) due to taking antibiotics.

Special warnings regarding use of the medicine
Before treatment with Calinda Vaginal Ovules, tell your doctor if:

- you have diarrhoea or usually get diarrhoea when you take antibiotics
- you have a history of inflammatory bowel disease such as Crohn's Disease or Ulcerative Colitis

If you develop severe, prolonged or bloody diarrhea during or after using Calinda, consult your doctor immediately since it may be necessary to stop the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.

Consult your doctor if you can use this medicine if:

- you suffer from problems with the kidneys, liver or immune system.
- you are under 18 years of age or over 65 years of age.

Additional warnings regarding use of the medicine:
As with all vaginal infections, sexual intercourse during treatment with Calinda is not recommended. Calinda may reduce the effectiveness of condoms or diaphragms. Do not rely on condoms and contraceptive diaphragms during the course of treatment with the medicine and for 72 hours following treatment.
The use of other vaginal products such as tampons or vaginal washes during treatment with the medicine is not recommended.

Children and adolescents
There is no information regarding the safety and effectiveness of using this preparation in children and adolescents.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Medicines for muscle relaxation, as Calinda may increase the action of such medicines.

Pregnancy, breastfeeding, and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.
The use of Calinda in the first three months of pregnancy is not recommended as there is insufficient evidence of medicine safety.
If you are pregnant, Calinda may only be used after consultation with your doctor, who will decide if treatment with the medicine is appropriate for you.

If you are breastfeeding, your doctor will decide if Calinda is appropriate for you as the active substance may pass into breast milk.

Although it is not likely that a nursing infant will consume much of the active ingredient from the breast milk it drinks, if your baby suffers from bloody diarrhea or shows any signs of illness, tell your doctor immediately. You should stop breastfeeding if this happens.

Driving and using machines
This medicine is unlikely to affect the ability to drive and operate machines.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only. The recommended dosage of this medicine is one ovule inserted deep into the vagina, at night before bedtime for 3 consecutive nights. After insertion the ovule will melt and disappear.

Do not exceed the recommended dose.
Attention - Do not swallow!

Do not use the preparation if the plastic pack containing the ovule is torn, open or not completely sealed.
Take care not to warm the ovule since warming may soften it and distort its shape.

Manner of use:

- Remove the ovule from the plastic pack.
- Lie on your back with the knees bent towards the chest.
- Insert the ovule into the vagina with the tip of your third (middle) finger, as deep as possible without causing discomfort.

Always wash your hands after using the ovules.

If you have accidentally used a higher dosage, tell your doctor. Do not use any more ovules until your doctor tells you to.
If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you swallow Calinda
If the ovule has been swallowed or eaten, contact your doctor. The ovules are not likely to cause any harm, but your doctor will be able to give you advice on what to do.

If you forgot to use the medicine, and the forgotten ovule is just a few hours late, use the ovule as soon as you remember.

If it is time for the next ovule, skip the forgotten one. Do not take a double dose. Take the next ovule at the normal time and consult the doctor.

Continue using the ovules at the usual times.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Calinda may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
Tell your doctor immediately if you:

- develop severe, persistent or bloody diarrhea (which may be accompanied by abdominal pain or fever). This is an uncommon side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation or inflammation of the large intestine wall (pseudomembranous colitis).
- experience a severe allergic reaction or skin reactions. These are very rare side effects.

Common side effects (occur in 1-10 in 100 users):

- fungal infections, yeast infection
- headache
- abdominal pain, diarrhoea, nausea
- itching (non-application site)
- vaginal thrush, vaginal discomfort, vaginal disorder

Uncommon side effects (occur in 1-10 in 1000 users):

- vomiting
- rash
- upper abdominal pain or back pain
- fever or chills, feeling sick (malaise)
- painful urination, blood in the urine, cloudy or foul-smelling urine, increased frequency or urgency of urination
- vaginal infection, vaginal discharge, irregular periods
- pain (application site), itching, localized swelling

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Hard fat

What the medicine looks like and contents of the pack:
Cream-yellowish ovules.
Each pack contains 3 ovules packed in a plastic wrap.

Registration holder and address:
Halperin N. H. Medic Ltd., 19 Tzur Street, Ma'ayan Tzvi, 3080500, MP Hof Carmel.

Manufacturer's name and address:
Lavipharm S.A .
Agias Marinas str. Paiania Attiki, P.O. 59, 19002, Greece

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 167-92-36117-00

Revised in August 2021 according to MOH guidelines.