

Item Name:

AVOCIN VAGINAL CREAM 40 g- Leaflet



AVOCIN
2% VAGINAL CREAM
Clindamycin Phosphate
Equivalent to 2% w/w Clindamycin

Composition:

Avocin 2% Vaginal Cream contains Clindamycin Phosphate (equivalent to 2% w/w Clindamycin).

Pharmacological Action:

Clindamycin Phosphate is a synthetic antibiotic produced from lincomycin.

Mechanism of action:

Clindamycin Phosphate is hydrolyzed in vivo to Clindamycin, which inhibits bacterial protein synthesis. It binds to the 50S subunit of the bacterial ribosome and thereby prevents peptide bond formation.

Microbiology: Clindamycin is an antimicrobial agent which has been shown to have in vitro activity against the following organisms which are associated with bacterial vaginosis:

Gardnerella vaginalis

Mobiluncus spp

Mycoplasma hominis

Peptostreptococcus spp

Pharmacokinetics:

Following once a day dosing of 100mg of vaginally administered Clindamycin, at a concentration equivalent to 20mg of Clindamycin per gram of cream, peak serum Clindamycin levels average 20 ng/ml (range, 3 to 93 ng/ml) in normal volunteers. Approximately 3% (range, 0.1 to 7%) of the administered dose is absorbed systemically. In woman with bacterial vaginosis, the amount of clindamycin absorbed following vaginal administration of 5 grams of Avocin 2% Vaginal Cream is 4% (range, 0.8 to 8%) which is approximately the same as in normal volunteers.

Indications:

Avocin 2% Vaginal Cream is indicated in the treatment of symptomatic bacterial vaginosis (formerly referred to as haemophilus vaginitis, gardnerella vaginitis, corynebacterium vaginitis or anaerobic vaginosis) in non-pregnant women.

Other pathogens commonly associated with vulvovaginitis e.g. Trichomonas vaginalis, candida albicans, chlamydia trachomatis, neisseria gonorrhoeae and herpes simplex virus should be ruled out by appropriate methods.

Contraindications:

Avocin 2% Vaginal Cream is contraindicated in patients with a history of hypersensitivity to Clindamycin or lincomycin.

Incompatibilities:

Avocin 2% Vaginal Cream contains mineral oil that may weaken latex or rubber products, such as condoms or vaginal contraceptive diaphragms, and make them less effective as barrier method of contraception or as protection from sexually transmitted diseases. The use of such products within 72 hours following treatment with Avocin 2% Vaginal Cream is not recommended.

Special Precautions:

- Clindamycin has been associated with diarrhoea and in some cases pseudomembranous colitis.

Minimal absorption (approximately 4%) occurs following the use of clindamycin phosphate cream intravaginally, however, if significant or prolonged diarrhoea occurs, the drug should be discontinued and appropriate diagnostic procedures and treatment provided as necessary.

- Safety in pregnancy and lactation has not been established.

- Avocin 2% Vaginal Cream for intravaginal use only.

Interactions:

Cross-resistance has been demonstrated between clindamycin and lincomycin. Antagonism has been demonstrated between Clindamycin and erythromycin in vitro.

Dosage and directions for use:

Dosage:

The recommended dose is one applicatorful (approximately 5 grams, which is equivalent to 100 mg of Clindamycin), of cream intravaginally, preferably at bedtime, for 3 to 7 consecutive days. Concomitant use with other intra-vaginal products is not recommended.

Directions for use:

1. Plastic disposable applicators are provided with this package. They are designed to allow proper vaginal administration of the cream.

2. Unscrew cap and aluminum seal from cream tube. Screw a plastic applicator on the threaded end of the tube.

3. Rolling tube from the bottom, squeeze gently and force the medication into the applicator. The applicator is filled when the plunger reaches its pre-determined stopping point.

4. Unscrew the applicator from the tube and replace the cap.

5. While lying on your back, firmly grasp the applicator barrel and insert into vagina as far as possible without causing discomfort.

6. Slowly push the plunger until it stops.

7. Carefully withdraw applicator from the vagina, and discard the applicator.

8. Shelf life after first opening is 30 days.

Side Effects:

Vaginal irritation or itching, increased white discharge from the vagina, dizziness, headache, heartburn, nausea, vomiting, constipation, pain in the lower abdomen, diarrhea, skin rash and urticaria.

Storage Conditions:

Store below 25° C. Protect from freezing. Keep out of reach of children.

Presentation:

Avocin 2% Vaginal Cream is available in laminated tube of 40 gm, accompanied with 7 disposable applicators.

THIS IS A MEDICAMENT

-Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
-The doctor and the pharmacist are experts in medicines, their benefits and risks.
-Do not by your self interrupt the period of treatment prescribed for you.
-Do not repeat the same prescription without consulting your doctor.
-Keep all medicaments out of reach of the children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

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Produced By :

Middle East Pharmaceutical Industries Co. Ltd. (Avalon Pharma), Riyadh, Saudi Arabia, Tel +966 (11) 2653948