1. NAME OF THE DRUG PRODUCT : CHI GYNO-CARE

Pharmaceutical Dosage Form: Soft Gelatin Vaginal Ovules

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

2.1 Qualitative Declaration :

The active ingredient shall be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.

Each Soft Gelatin Capsule Contains:
Neomycin Sulfate USP ……..50.2 mg

(as 35 mg or 35,000 I.U. Neomycin)

Polymyxin B Sulfate USP…….. 35,000 I.U.

Nystatin USP……..100,000 I.U.

Excipients ……....q.s. Approved

Colour Used in Softgel Capsule Shell.

2.2 Quantitative Declaration

Quantity of active ingredient must be expressed per dosage unit (for metered dose inhalation product, per puff), per unit volume or per unit of weight.

Each Soft Gelatin Capsule Contains:
Neomycin Sulfate USP ……..50.2 mg

(as 35 mg or 35,000 I.U. Neomycin)

Polymyxin B Sulfate USP…….. 35,000 I.U.

Nystatin USP……..100,000 I.U.

Excipients ……....q.s. Approved

Colour Used in Softgel Capsule Shell.

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM :

Oval Shape White Opaque colored soft gelatin capsule containing off white to white colored oily suspension for vaginal Use.

4. CLINICAL PARTICULARS:

4.1 THERAPEUTIC INDICATIONS:

Suppurative leucorrhoea caused by vaginal candidasis, nonspecific bacterial vaginitis, vulvitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adult : Insert deeply 1 capsule of CHI GYNO-CARE into the vaginal daily for 6 days in the evening.

In case of severe or chronic infection, administer 1-2 capsule of CHI GYNO-CARE daily for 6-12 days in the morning and the evening

4.3 CONTRAINDICATIONS

Hypersensitivity to neomycin, the polymyxins, Nystatin or any ingredient in the Formulation is a contraindication to its use. A history of hypersensitivity or serious toxic reaction to an aminoglycoside may also contraindicate the use of any other aminoglycoside because of the known cross-sensitivity of patients to drugs of this class.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Ototoxicity, nephrotoxicity, and neuromuscular blockade may occur if Neomycin and Polymyxin B Sulfates Solution for Irrigation ingredients are systemically absorbed Absorption of neomycin from the denuded bladder surface has been reported. Patients with impaired renal function, infants, dehydrated patients, elderly patients, and patients receiving high doses of prolonged treatment are especially at risk for the development of toxicity.

Long-term treatment with CHI GYNO-CARE is not recommended because it may increase the risk of selection for resistant strains. People with kidney disease should consult their doctor before taking CHI GYNO-CARE. Use caution when using CHI GYNO-CARE for women who are breastfeeding. The article has provided information on what CHI GYNO-CARE is, dosage and precautions for use. To ensure safety for health and maximize the effectiveness of treatment, patients need to take CHI GYNO-CARE medicine exactly as directed by their doctor. Store CHI GYNO-CARE medicine in a dry place, the temperature does not exceed 30 degrees Celsius and out of the reach of small children

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

CHI GYNO-CARE may have an interaction reaction if used concurrently with:

Spermicides because of possible increased risk of inactivation; Contraceptive pills.

4.6 FERTILITY, PREGNANCY AND

LACTATION Pregnancy:

Aminoglycosides, when absorbed, can cause fetal harm when administered to a pregnant woman. Aminoglycoside antibiotics cross the placenta and there have been several reports of total, irreversible, bilateral, congenital deafness in children whose mothers received streptomycin during pregnancy. Although serious side effects have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists. If Neomycin and Polymyxin B Sulfates Solution for Irrigation is used during pregnancy, the patient should be apprised of the potential hazard to the fetus.

Lactation:

A decision should be made to discontinue breastfeeding or discontinue the drug, taking into account the importance of the drug to the mother.

Excreted into human milk:

Unknown Excreted into animal milk: Yes **Comments**:

-Breastfed infants should be monitored for gastrointestinal effects (e.g., diarrhea, candidiasis [thrush, diaper rash], possible antibiotic-associated colitis indicated by blood in the stool).

-Other aminoglycoside antibiotics are excreted into human milk.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effects on the ability to drive and use machines have been performed.

4.8 ADVERSE REACTION:

Neomycin Sulfate, Polymyxin B Sulfate

Irritation of the urinary bladder mucosa has been reported.

Signs of ototoxicity and nephrotoxicity have been reported following parenteral use of these drugs and following the oral and topical use of neomycin

Nystatin:

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

Rare

Vaginal burning or itching not present before use of this medicine

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

4.9 OVERDOSE

-Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of CHI GYNO-CARE, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

-Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

-Please consult your physician or pharmacist or product package for more information.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

Neomycin sulfate:

Neomycin mediates its bactericidal action by inhibiting bacterial protein synthesis, thereby suppressing the growth and survival of susceptible bacteria. Following oral administration, the duration of bactericidal activity of neomycin ranged from 48 to 72 hours.5 By decreasing colonic bacteria that produce ammonia, neomycin was shown to be effective as an adjunctive therapy in hepatic coma to improve neurologic symptoms.

Like other aminoglycoside antibiotic drugs, neomycin inhibits bacterial ribosomes by binding to the 30S ribosomal subunit of susceptible bacteria and disrupting the translational machinery of bacterial protein synthesis.3,4 Bacterial translation is normally initiated by the mRNA binding to the 30S ribosomal subunit and subsequent binding with 50S subunit for elongation

Polymyxins B Sulfate:

Polymyxins are bactericidal drugs that bind to lipopolysaccharides (LPS) and phospholipids in the outer cell membrane of gram-negative bacteria. They competitively displace divalent cations from the phosphate groups of membrane lipids, which leads to disruption of the outer cell membrane, leakage of intracellular contents, and bacterial death.

In addition to their bactericidal effect, the polymyxins can bind and neutralize LPS and may reduce the pathophysiologic effects of endotoxin in the circulation.

Nystatin:

Nystatin is a channel-forming ionophore, meaning it exerts its therapeutic effect via formation of a membrane-spanning pore in the fungal plasma membrane. The formation of this pore results in a change in membrane permeability that allows for leakage of intracellular contents and the subsequent disruption of electrochemical gradients necessary for proper cell function.8,2 Selectivity for fungal cells over mammalian cells is due to nystatin's greater binding affinity for ergosterol, a key sterol found in fungal cell walls, as opposed to its mammalian counterpart, cholesterol.

5.2 PHARMACOKINETIC PROPERTIES

Neomycin Sulfate:

Absorption

Neomycin is poorly absorbed from the gastrointestinal tract. Gastrointestinal absorption of the drug may be increased if inflammatory or ulcerative gastrointestinal disease is present.

Distribution

The small fraction of absorbed neomycin is rapidly distributed in the tissues. The amount of systemically absorbed neomycin is reported to increase cumulatively with each repeated dose administered until a steady state is reached.

Metabolism

There is limited information on the metabolism of neomycin, as there is limited systemic absorption following drug administration. Metabolism is deemed to be negligible.

Elimination

The small absorbed fraction of neomycin is excreted by the kidney. The unabsorbed portion of the drug is excreted unchanged in the feces.

Polymyxin B:

Absorption

Administration by the oral route does not lead to absorption

Distribution

1 compartment models estimate the volume of distribution to be 34.3L to 47.2L However, the general consensus is that the volume of distribution is yet to be determined

Metabolism

There is little data available for the metabolism of polymyxin B. In one study, <1% of polymyxin B was eliminated through the kidneys and it had not been metabolised. Polymyxin B

has also been found in bile, not having undergone metabolic processes

Elimination

Polymyxin B is proposed to be primarily eliminated through renal tubular reabsorption and non-renal pathways Urine collection in humans and animals show <5% of polymyxin B eliminated from the kidneys. However, a Canadian product monograph states the drug is primarily eliminated through the kidneys and that 60% of polymyxin B is recovered in the urine. This discrepancy can be explained by the 12 to 24 hour lag time between administration and significant elimination of polymyxin B. Non-renal elimination is not well understood but all 4 components of polymyxin B have been detected in bile

Nystatin:

Absorption

Systemic absorption of nystatin is minimal following oral administration, and no detectable plasma concentrations are attained following topical or vaginal administration.

Distribution

Nystatin is not absorbed into the systemic circulation and thus does not undergo distribution.

Metabolism

Because nystatin undergoes little-to-no systemic absorption it is not metabolized to any appreciable extent.

Elimination

The majority of orally administered nystatin is eliminated unchanged in the feces.

6. PHARMACEUTICAL PARTICULARS :

6.1 List of Excipients:

Sr. No.	Ingredients	Specification
1	Light Liquid Paraffin	BP
2	Soft Paraffin (White)	BP
3	Gelatin	BP
4	Glycerol	BP
5	Sorbitol Solution (70%) (Non Crystallising)	BP
6	Methyl Hydroxybenzoate	BP
7	Propyl Hydroxybenzoate	BP
8	Titanium Dioxide	BP

9	Purified Water	BP

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Preserve in tight container, not exceeding 30°C. Keep out of reach of children.

6.5 NATURE AND CONTENTS OF CONTAINER

6 softgels are packed in Alu-PVC blister. Such a 1 blister is packed in printed carton along with pack insert

7. MARKETING AUTHORIZATION HOLDER:

OLIVE HEALTHCARE

197/2, Athiyawad,

Dabhel Village, Daman

India.

8. MARKETING AUTHORIZATION NUMBER:

Nil

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION :

NIL

10. DATE OF REVISION OF THE TEXT :

NIL