SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GOGYNAX (Clotrimazole Vaginal Inserts USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of constituent	Quantity per Tablet in mg	% of each ingredient is expressed as a percentage	Quantity in kg	% of each ingredient is expressed as a percentage	Role of ingredient
Clotrimazole USP	100.00	10.10	30.00	10.10	Active Ingredient
Microcrystalline Cellulose BP	440.00	44.44	132.00	44.44	Inactive
Sodium Starch Glycolate BP	20.000	2.020	6.00	2.020	Inactive
Maize Starch * BP	329.00	32.23	98.700	32.23	Inactive
Maize Starch BP (Paste)*	77.080	7.78	23.124	7.78	Inactive
Purified Water	----	---	---	---	Inactive
LUBRICATION					
Sodium Starch Glycolate BP	10.000	1.01	3.000	1.01	Inactive
Microcrystalline Cellulose BP	10.000	1.01	3.000	1.01	Inactive
Maize Starch BP	10.000	1.01	3.000	1.01	Inactive
Colloidal Anhydrous Silica BP	20.000	2.02	6.000	2.02	Inactive
Purified Talc BP	2.000	0.20	0.600	0.20	Inactive
Magnesium Stearate BP	2.000	0.20	0.600	0.20	Inactive

*Includes 8.0 % extra to compensate for LOD. Maize starch additionally added = 9.024 kg

USP: United States Pharmacopoeia

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

Inserts/Tablets (Vaginal)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clotrimazole vaginal tablets are indicated for the treatment of candidal vaginitis

4.2 Posology and method of administration

Gogynax Vaginal tablet: • One tablet to be inserted in the vagina, preferably at night for six consecutive days or alternatively 2 tablets at night, for 3 consecutive days.

- In recurrence a second treatment of 2 Gogynax tablets, preferably at night can be inserted in the vagina safely for 6-12 days.

Note: • Insertion of the tablet is best achieved when lying back with the legs slightly drawn up.

- It can be used even during menstruation although it is recommended that treatment should be timed so as to avoid the menstrual period.
- Gogynax Vaginal Tablets are odourless, colourless and do not stain the underwear.
- Recurrence is common if the full course of treatment is not completed.

4.3 Contraindications

Gogynax is not suitable to those who have shown allergy to clotrimazole

4.4 Special warnings and precautions for use

Gogynax Vaginal Tablets may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

Pregnant women: Vaginally applied Gogynax should be used during pregnancy if clearly needed and only under the supervision of a healthcare provider. There are no adequate studies to support its use during first 3 months of pregnancy.

Nursing mothers: Gogynax is safe in nursing mothers

Children: Gogynax is not recommended in children below the age of 3 years

4.6 Pregnancy and lactation

Pregnant women: Vaginally applied Gogynax should be used during pregnancy if clearly needed and only under the supervision of a healthcare provider. There are no adequate studies to support its use during first 3 months of pregnancy.

Nursing mothers: Gogynax is safe in nursing mothers

4.7 Adverse reactions

Gogynax Vaginal Tablets are well-tolerated and however it may cause the following side effects: vomiting, vaginal soreness with sexual intercourse, vaginal irritation, itching and dyspareunia (pain that can happen during sexual intercourse), clitoral (female sex organ) irritation, dysuria (Painful Urination), vulval irritation, lower abdominal (stomach) cramps, slight cramping, slight increase in urinary frequency, and burning or irritation of genitals in the sexual partner.

4.8 Symptoms of over dosage & treatment

No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal or dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity.

Pharmacological Action:

Gogynax is a broad-spectrum anti-fungal and trichomonacide agent from an imidazole class of medicine.

5.2 Pharmacokinetic properties

Absorption of Clotrimazole from the vagina following administration as a vaginal tablet is 3-10%. Fungicidal concentrations of clotrimazole are found in the vaginal fluid up to 3 days after the application of one vaginal tablet. In contrast plasma levels of clotrimazole up to 72 hours after application are lower than 0.01 μg/ml, demonstrating that clotrimazole is rapidly metabolised and does not lead to measurable systemic effects or side effects..

Binding of clotrimazole to blood serum proteins is about 98% in the undiluted serum, due to its highly hydrophobic properties.

Clotrimazole is metabolised in the liver via oxidation and degradation of the imidazole cycle (desamination, O-desalkylation). Thus inactive hydroxy derivatives occur. These agents are mainly excreted via the gallbladder with the faeces.

The elimination half-life of clotrimazole is 3.5-5 hours.

6. PHARMACEUTICAL PERTICULARS

6.1 List of excipients

Name of Excipient	Quality of Excipient
Microcrystalline Cellulose	BP
Sodium Starch Glycolate	BP
Maize Starch *	BP
Maize Starch (Paste)*	BP
Microcrystalline Cellulose	BP
Sodium Starch Glycolate	BP
Colloidal Anhydrous Silica	BP
Purified Talc	BP
Magnesium Stearate	BP

6.2 Incompatibilities

Incompatibilities will depend on the nature of the drug added.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

Gogynax is available in Aluminum- PVC blister pack of 6 Tablets, are packed in monocarton along with applicator & Leaflet. Such 20 monocartons are packed in one outer carton.

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE

E-mail – gauri.amerkar@shalina.com

Website: www.shalina.com.

8. MARKETING AUTHORISATION HOLDER IN OTHER COUNTRIES

Product is registered in Ghana, Nigeria, Zambia, and D. R. Congo & Central African Republic.