**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**
Gastro-intestinal disturbances and central nervous system depression may follow accidental oral ingestion. Treatment is symptomatic and supportive.

**DRUG INTERACTIONS:**
Not known.

**STEPS FOR USING APPLICATOR (Tablets)**

1- Pull out plunger until it stops.

2- Place the vaginal tablet into the applicator.

3- Insert applicator containing the tablet carefully and as deeply as possible into the vagina (preferably lying on your back).

4- Push the plunger until it stops, thereby depositing the tablet into the vagina.

5- Remove the applicator.

**اپلیکیٹر کو استعمال کرنے کا طریقہ:**

☆ پلنجر کو باہر کھینچیں جب تک رک نہ جائے۔

☆ گولی کو اپلیکیٹر میں رکھیں۔

☆ اپلیکیٹر کو vagina میں احتیاط کے ساتھ جتنا اندر رکھا سکتے ہیں رکھیں۔
(کمر کے بل لیٹ کر زیادہ بہتر ہوگا)۔

☆ پلنجر کو اتنا دبائیں کے گولی اندر چلی جائے۔

☆ اور اپلیکیٹر کو احتیاط سے باہر نکل لیں۔

**STEPS FOR USING APPLICATOR (Cream)**

Open tube and join it with applicator

Release cream in applicator by squeezing the tube gently untill plunger stops.

Remove applicator from tube. Insert the applicator inside vagina as deep as possible. Release cream by pressing the plunger. (Best result achieved by lying on back).

**اپلیکیٹر کو استعمال کرنے کا طریقہ:**

ٹیوب کھول کر اپلیکیٹر کے ساتھ منسلک کر لیں۔

اپلیکیٹر کو کریم سے آہستہ آہستہ مکمل بھر لیں۔

اپلیکیٹر کو ٹیوب سے علیحدہ کریں۔ Vagina میں اپلیکیٹر اندر تک ڈال کر Plunger کو دبائیں تا کہ کریم اندر چلی جائے اور اپلیکیٹر مکمل طور پر خالی ہو جائے۔ بہتر نتائج کے لئے یہ عمل لیٹی ہوئی پوزیشن میں کریں۔

**INSTRUCTIONS**
Dosage: As directed by the physician.
Store below 30°C in a dry place protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.
Not to be taken orally.

## ھدایات:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کھانے کیلئے نہیں ہے۔

**PRESENTATION**
***Oligyn*** 100 mg tablet Alu Alu pack 2 x 3's with applicator.
***Oligyn-1*** tablet Alu Alu pack 1 x 1's with applicator.
***Oligyn*** cream 35g and 60g tube with applicator.

***Manufactured by:***
***Platinum***
***Pharmaceuticals (Pvt.) Ltd.***
A 20,North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

QAR No. AW19-0435

# Oligyn

(Clotrimazole)

Vaginal Tablets and Cream

# اولیجن

(کلوٹرائمازول)

گولیاں اور کریم

**COMPOSITION:**

***Oligyn* 100mg Vaginal Tablets**
Each vaginal tablet contains:
Clotrimazole (U.S.P.) ..... 100 mg.
Product Complies (U.S.P.) Specs.

***Oligyn-1* Vaginal Tablets**
Each vaginal tablet contains:
Clotrimazole (U.S.P.) ..... 500 mg.
Product Complies (U.S.P.) Specs.

***Oligyn* Vaginal Cream**
A white cream containing 2% clotrimazole (U.S.P.) 1-(2-cholortrityl) Imidazole.
Product Complies (U.S.P.) Specs.

**MECHANISM OF ACTION**
Clotrimazole works to kill individual candida or fungal cell by altering the permeability of the fungal cell wall.It binds to phasphotipids in the cell membrane and inhibits the biosynthesis of ergostesrol and other sterols required for cell membrance production.
For the relief of vaginal itching,burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

**PHARMACOKINETICS**
Studies using $^{14}$C-labelled Clotrimazole (***Oligyn***) have shown absorption of about 3% of the administered dose from normal or inflamed vaginal mucosa (peak serum level of 0.03 mg / ml) 24 hours after insertion of 100mg vaginal tablet.

Studies in normal volunteers after vaginal insertion of one 500mg vaginal tablet showed that plasma levels of clotrimazole up to 10ng/mL were reached during the period of assay (up to 72 hours after insertion). Significant concentrations of Clotrimazole (***Oligyn***)

were present in vaginal secretions for up to 48 hours after insertion.

Pharmacokinetic investigations after vaginal application has shown that only a small amount of clotrimazole is absorbed. Due to the rapid hepatic metabolism of absorbed clotrimazole into pharmacologically inactive metabolization, the resulting peak plasma concentrations of clotrimazole after vaginal application of a 500mg dose were less than 10mg/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

**INDICATIONS**

A single course of one 500mg intravaginal Clotrimazole has produced 84% mycological cure of vaginal candidiasis. When a first course proved unsuccessful, a second course produced success in 8 of 12 women treated.

A single course of 100mg intravaginal Clotrimazole (Oligyn) has produced mycological cure of vaginal candidiasis as follows: one 100mg vaginal tablet daily for six days, 80% and two 100mg vaginal tablets daily for three days, 75%. When a first course proved unsuccessful, a second course produced success in 8 of 12 women treated.

It is also indicated for infections of the genital region (vaginitis) trichomonads and superinfections caused by clotrimazole-sensitive bacteria.

**DOSAGE AND ADMINISTRATION**

**For** Oligyn **100 mg Tablets:**
**Initial Infections**

In general, a 3-day treatment for Candida vaginitis will be sufficient. On three consecutive nights, Two Clotrimazole (Oligyn) 100mg Vaginal Tablets are inserted as deeply as possible into the vagina (see directions for use of applicator). This is best achieved when lying down with the knees slightly bent.

**Re-Infections**

In general a 6-day treatment will be sufficient. On six consecutive nights, one Clotrimazole ( *Oligyn* ) 100mg Vaginal Tablet is inserted as deeply as possible into the vagina even if symptoms disappear. If individual cases should require it, two vaginal tablets can be used daily, i.e. one in the morning and one in the evening for 6 - **12** days. Use even during menstruation, although it is recommended that the treatment should be timed so as to avoid the menstrual period and be finished before the onset of menstruation. For prevention of re-infection, the partner should be treated locally with Clotrimazole cream at the same time. Clotrimazole ( *Oligyn* ) 100mg Vaginal Tablets are odourless. colourless and do not stain the underwear. In individual cases where disintegration of the tablet does not occur, such as in dry vagina associated with menopause, it is recommended that clotrimazole vaginal cream be used.

**For** Oligyn-1 **Tablets**

In general, a single dose treatment will be sufficient for Candida vaginitis. The Clotrimazole (Oligyn-1) vaginal tablet should be inserted, preferably at night, into the vagina as deeply as possible (see instructions for the use of applicator). This is best achieved when lying back with the legs slightly drawn up. If necessary, a second treatment may be carried out. It is recommended that the treatment should be timed so as to avoid the menstrual period. In individual cases where disintegration of the tablet does not occur, such as in dry vagina associated with menopause, it s recommended that clotrimazole vaginal cream be used.

**For** Oligyn **Cream**

Insert one filled applicator (5g) intravaginally twice daily for three consecutive days or once daily for 6 consecutive days preferably at night.

**CONTRAINDICATIONS:**

Hypersensitivity to clotrimazole. Particular caution should be exercised in the case of vaginal use in the first three months of pregnancy.

**WARNINGS AND PRECAUTIONS**

i) Not for oral use.

ii) Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.

iii) If there is no improvement in 3 days or if symptoms have not disappeared within 7 days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.

iv) Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.

v) If symptoms recur within 2 months, consult a medical practitioner.

vi) If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medical practitioner.

vii) Do not use in girls under 12 years of age, except on the advice of a medical practitioner.

viii) If skin rash or new irritation occurs, discontinue use.

ix) Oligyn products may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS**

Local reactions including irritating and burning may occur. Contact allergic dermatitis has been reported. In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur. Clotrimazole Vaginal Tablet should not be administered to pregnant women during the first trimester, since the safety in this regard has not been established. During pregnancy, the Clotrimazole Vaginal Tablet should be inserted without using an applicator. Clotrimazole Vaginal Tablet may only be used during pregnancy on the advice of a medical doctor. The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.

In isolated cases there may be generalised hypersensitivity reactions of varying degrees of severity. These reactions may affect the skin (e.g. itching, redness), breathing (shortness of breath), the circulation (e.g. a drop in blood pressure requiring treatment or even impaired consciousness) or the gastrointestinal tract (e.g.nausea, diarrhoea).