

PACKAGE LEAFLET: INFORMATION FOR THE USER

Protogyn[®] 500 mg Film-Coated Tablets

Active substance: Tinidazole.

Read all of this leaflet carefully before you start using this medicine.

- **Keep this leaflet. You may need to read it again**
- **If you have any further questions, ask your doctor or pharmacist**
- **This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours**
- **If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

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1. What Protogyn is and what it is used for

-Pharmacotherapeutic group:

Protogyn[®] (Tinidazole) is an anti-protozoal and anti-anaerobic drug that exerts its activity by penetration into the cell of the microorganisms and subsequent damage of DNA strands or inhibition of their synthesis.

Protogyn[®] is active against:

Protozoa: Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia.

Anaerobic bacteria: Bacteroides fragilis, Bacteroides spp., Fusobacteria spp., Peptococcus spp., Clostridium spp., Eubacterium spp., Veillonella spp. and Gardnerella vaginalis.

-Therapeutic Indications

Protogyn[®] is indicated for the treatment of the following infections:

Anaerobic infections such as:

- Bacterial septicemia.
- Chronic sinusitis, pneumonia and pulmonary abscess.
- Postoperative abdominal infections.
- Gynecological infections.
- Bacterial vaginosis.
- Peritonitis.
- Cellulitis.
- Osteomyelitis due to Bacteroides.

Protozoal infections such as:

- Urogenital trichomoniasis in both male and female patients.
- Giardiasis.
- Intestinal amoebiasis.
- Amoebic involvement of the liver.
- Acute ulcerative gingivitis.

Prophylaxis:

Prevention of postoperative infections caused by anaerobic bacteria especially those associated with colonic, GI and gynecological surgery.

2. Before you use Protogyn

a- Do not use Protogyn:

- If You are hypersensitive to tinidazole or any of the other ingredients of Protogyn.
- If You having or with a history of blood dyscrasia.
- If You with organic neurological disorders.

b- Take special care with Protogyn:

- Tinidazole has been associated with neurological disturbances such as: Dizziness, vertigo, ataxia and peripheral neuropathy. So, if any abnormal neurological signs developed, the drug should be discontinued.
- Concomitant use of alcoholic beverages causes abdominal cramps, flushing and vomiting, as a result of disulfiram-like reaction.

Vaginal Candidiasis:

- The use of tinidazole may result in candida vaginitis. In a clinical study of 235 women who received tinidazole for bacterial vaginosis, a vaginal fungal infection developed in 11 (4.7%) of all study subjects.

Drug Resistance:

- Prescribing **Protogyn** in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

c-Taking other medicines:

- Alcohol: alcohol beverages should be avoided during treatment, because of the possibility of disulfiram-like reaction.
- Coumarin anticoagulants: Tinidazole may potentiate the effects of coumarin anticoagulants.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

d- Taking Protogyn with food and drink:

It is recommended to take **Protogyn** during or after a meal.

e-Pregnancy and breast-feeding:

Pregnancy: Tinidazole should not be used during the first trimester of pregnancy.

Lactation: Tinidazole should not be given to a breast feeding woman.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

3. How to use Protogyn

Always use **Protogyn** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Dosage and administration:

Anaerobic Infections: an initial dose of 2g in the first day, followed by 1g daily given as a single dose or 500 mg twice daily. Duration of treatment is 5-6 days, but clinical judgment must determine the duration of therapy.

* Clinical data are not available to allow dosage recommendations for children below the age of 12 years in the treatment or the prevention of anaerobic infections.

Bacterial vaginosis: a single dose of 2g.

Acute ulcerative gingivitis: a single dose of 2g

Urogenital trichomoniasis: Adults: a single dose of 2g. Children: a single dose of 50-75mg/kg. In some cases, dosage should be repeated once.

Giardiasis: Adults: a single dose of 2g. Children: a single dose of 50-75mg/kg. In some cases, dosage should be repeated once.

Intestinal amoebiasis: Adults: 2g daily for 2-3 days, and may be continued up to 6 days if a three-day single dose is ineffective. Children: dose of 50-60mg/kg daily for 3 days.

Amoebic involvement of liver: Adults: dose of 1.5-2 g daily for 3-6 days. Children: 50-60mg/kg daily for 5 days.

Abdominal surgery prophylaxis: a single 2g dose approximately 12 hours before surgery.

-If you take more **Protogyn** than you should:

There is no specific antidote for the treatment of Tinidazole overdose.

Treatment is symptomatic, and supportive. Gastric lavage may be useful. Tinidazole is easily dialyzed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **Protogyn** can cause side effects, although not everybody gets them.

The side effects are:

- Mild gastrointestinal side effects, including: Anorexia, metallic taste, diarrhea, nausea and vomiting may occur.
- Allergic reactions may occur in rare cases including: Skin rash, pruritus, urticaria and angioneurotic edema.
- Others include: Dizziness, vertigo, ataxia, headache, tiredness and dark urine.
- Transient leucopenia may occur.

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Protogyn

- Keep out of the reach and sight of children.
- Store below 30 C
- Do not use **Protogyn** after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

a-What Protogyn Tablet contains:

- The active substance** : Tinidazole
- The other ingredients** : Sodium lauryl sulfate, povidone, microcrystalline cellulose, croscarmellose sodium, talc, FD & C yellow No. 6, lactose monohydrate, hypromellose, titanium dioxide, polyethylene glycol.

b-What Protogyn looks like and contents of the packs:

Protogyn® F.C. tablets: Each film-coated tablet contains 500 mg Tinidazole B.P in packs of 4 tablets

Protogyn is made by:
Hayat Pharmaceutical Industries Co. PLC
P.O.Box 1564
Amman 11118 Jordan

This leaflet was last approved in 7/2012

(This is a medicament-keep medicaments out of the reach of children.)

- Medicament is a product that 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 dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.