



AGOG **Pharma Ltd.**

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, Thane Vashi Taluka Industrial Co-op. Estate Ltd. Gaumapada, Vasai (E), Dist. Thane - 401 208, INDIA.
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LEAFLET

AGOMETROL

Metronidazole Oral Suspension / Tablets BP

COMPOSITION

Each tablet contains 250 mg Metronidazole.

Metronidazole (250 mg) equivalent to 250 mg Metronidazole BP.

Tablets : Each tablet contains 250 mg Metronidazole BP 250 mg.

PHARMACOLOGICAL CLASSIFICATION

Anti-Parasitic & Anti-Microbial Agent.

PHARMACOLOGICAL ACTIONS

Metronidazole is an orally effective, oral amebicide against Entamoeba histolytica, Giardia lamblia, Trichomonas vaginalis. It is also used against intestinal helminths like Ascaris lumbricoides, Trichuris trichiura and hookworms. It has complete cure rate in amoebic dysentery (cure rate of 100% for amoebae load of 100 million/ml of stool), trichomoniasis (cure rate of 90%) and giardiasis (cure rate of 90%).

INDICATIONS

The present product contains Metronidazole which is effective against amoebic dysentery, Giardiasis, Trichomoniasis, helminths, certain protozoal infections, including protozoal dysentery, amoebic dysentery, giardiasis, trichomoniasis, intestinal helminths like Ascaris lumbricoides, Trichuris trichiura and hookworms.

HOUSING

All forms of intestinal helminths and intestinal protozoa.

STANDARD

Pharmacopoeia of India.

CONTRAINDICATIONS

This drug is contraindicated in patients with a known history of hypersensitivity to Metronidazole or its metabolites. Metronidazole is contraindicated in patients with known hypersensitivity to furazolidone, chloramphenicol.

WARNINGS

Contraindicated in pregnant women. The under contraindicated in pregnant women or if there is any sign of pregnancy, have been caused by patients treated with this medicine. The association of metronidazole with birth defects has been reported. Do not use in pregnant women. If the need to use this drug in pregnant patients, it can be done only after consulting a doctor.

PREGNANCY

Contraindicated in pregnant women. The under contraindicated in pregnant women or if there is any sign of pregnancy, have been caused by patients treated with this medicine. The association of metronidazole with birth defects has been reported. Do not use in pregnant women. If the need to use this drug in pregnant patients, it can be done only after consulting a doctor.

Metronidazole is contraindicated in patients with known hypersensitivity to furazolidone, chloramphenicol or any other metronidazole containing drugs.

ADVERSE REACTIONS

Uncommon side effects in the stools may include nausea, vomiting, diarrhoea, abdominal cramps and/or epigastric pain, abdominal cramps, headache, dizziness, tinnitus, ringing of the ears, taste disturbance, sore throat, fever, rash, conjunctivitis, conjunctival discharge, conjunctival haemorrhage, etc. These reactions are usually self-limiting.

During treatment rarely, peripheral neuropathy, a few instances of peripheral neuropathy have been reported. In patients taking formulations have been reported.

DOSAGE AND ADMINISTRATION

In adults : Metronidazole is orally given in dose of 400 to 600 mg thrice daily for 5 to 10 days. Children aged between 1 to 3 years may be given 100 mg daily, children aged between 3 to 7 years, 200 mg daily, children aged between 7 to 10 years and full the adult dose.

For topical : The usual dose is 200 mg twice daily for 7 days or as directed.

For vaginal : Metronidazole gel vaginal ring at a single application of 2 doses (200 mg each) is given every 48 hours for 10 days. Gel 1 pattern should be avoided consecutively.

Anterior blepharitis : 2 drops of 0.5% solution 2 to 3 times daily in a dose of 100 mg to 200 mg every 8 hours for 7 days or as directed by a doctor.

STORAGE

Store under normal atmospheric conditions (20° - 30°C). Protect from light. Avoid direct sunlight or intense light.

For suspension : Shake well before use.

PRESENTATION

Suspension : Bottles of 200 ml, 100 ml and 50 ml bottles.

Tablets : Bottles of 100 x 10, 50 x pack of 1000 tablets.

Oral suspensions of 100 x 10 tablets.

Manufactured by



AGOG PHARMA LTD.
Plot No. 33, Sector II, Thane Vashi Taluka Industrial Co-op. Estate Ltd.,
Vasai (E), Dist. Thane, (M.H.)



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1.5.3 Patient information leaflet (PIL)

AGOMETROL

Metronidazole Oral Suspension / Tablets BP

COMPOSITION

Each tablet contains 250 mg Metronidazole.

Metronidazole (Metronidazole BP equivalent) 250 mg.

Tablets : Each tablet contains 250 mg Metronidazole BP 250 mg.

PHARMACOTHERAPEUTIC CLASSIFICATION

Anti-parasitic & anti-microbial agent.

PHARMACOLOGICAL ACTIONS

Metronidazole is an orally effective, oral amebicidal agent. It has bactericidal, Protozoal, Fungicidal, antiprotozoal and TBC curative properties. It is capable of action against both anaerobic bacteria with 200 µg/ml minimum inhibitory concentration and against anaerobic protozoa such as Giardia lamblia, Entamoeba histolytica and Trichomonas vaginalis. Metronidazole inhibits DNA synthesis and thus, kills the microorganism.

INDICATIONS

The present product contains Metronidazole 250 mg tablets. It is indicated for the treatment of Giardiasis, helminths, protozoa, skin diseases, mucocutaneous, pelvic diseases, protozoal vaginitis, gonococcal and trichomonal infections. It is also indicated in the therapy of amoebic dysentery and liver abscess.

No specific use.

All forms of anaerobic bacterial and mucocutaneous disease.

Standard.

Protozoal vaginitis.

CONTRAINdications

This drug is contraindicated in patients with a known history of hypersensitivity to Metronidazole or its metabolites. Metronidazole is contraindicated in patients with known hypersensitivity to sulfonamides and barbiturates.

Warnings

Contraindicated in pregnant women. The tablet contains lead. There may be cases of central nervous system toxicity, hence it is avoided by patients having liver disease. The association of metronidazole with peripheral neuropathy has been reported. Metronidazole should not be administered to patients with known sensitivity against disulfiram.

PREcautions

Contraindicated in patients who have hepatic disease, a non-delivery condition of Metronidazole and in combination of Carbamazepine and its metabolites. The present product has logos placed by Indian pharmaceutical

Ministry of Health for safety, quality and standard. Metronidazole is indicated in treatment of amoebic dysentery and liver abscess.

ADVERSE REACTIONS

Uncommon side effects in the treated group include nausea, vomiting, diarrhoea, abdominal cramps and in patients occur occasionally, headache, loss of taste, body aches, fever, rash, blisters, redness, conjunctivitis, conjunctival discharge, etc. Metronidazole is relatively safe from reported toxicity.

During treatment rarely, periorificial Metronidazole Rash, a few instances of peripheral neuropathy. In patients taking form tablets have been reported.

DOSAGE AND ADMINISTRATION

In adults : Metronidazole 250 mg orally in case of 400 to 600 mg thrice daily for 5 to 10 days. Children aged between 1 to 3 years may be given 100 mg orally twice between 3 to 7 years, and 200 mg thrice daily between 7 to 10 years and full the adult dose.

Important : The dosage is 250 mg orally twice daily for 5 to 10 days.

Children : Metronidazole 250 mg orally twice daily for 5 to 10 days.

Adults : Metronidazole 250 mg orally twice daily for 5 to 10 days.

Oral suspension : Metronidazole 250 mg orally twice daily for 5 to 10 days.

Oral suspension : Metronidazole 250 mg orally twice daily for 5 to 10 days.

PRESENTATION

Suspension : Bottle of 200 ml, a powder and oral tablets.

Tablets : Strip of 10 x 10, 100 pack of 1000 tablets.

Oral suspension : 1000 ml.

Manufactured by



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