SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ADCO-METRONIDAZOLE 200 mg tablet

ADCO-METRONIDAZOLE 400 mg tablet

COMPOSITION

Each **ADCO-METRONIDAZOLE 200 mg** tablet contains metronidazole 200 mg

Each **ADCO-METRONIDAZOLE 400 mg** tablet contains metronidazole 400 mg

Excipients: Gelatin (grade 50), magnesium stearate, maize starch, microcrystalline cellulose pH 101, sodium starch glycolate.

Sugar free

CATEGORY AND CLASS

A: 20.2.6 Medicines against protozoa

PHARMACOLOGICAL ACTION

Metronidazole is an antiprotozoal agent effective against *Trichomonas vaginalis, Entamoeba histolytica* and in giardiasis. Metronidazole is useful for the treatment of infections caused by various anaerobic bacteria, particularly *Bacteroides fragilis*.

INDICATIONS

- Urogenital trichomoniasis

- Amoebiasis
- Giardiasis
- Ulcerative gingivitis (Vincent's infection)
- Infections caused by anaerobic bacteria, especially *Bacteroides fragilis*.

As a prophylactic in postsurgical abdominal and pelvic infections.

CONTRAINDICATIONS

- Hypersensitivity to metronidazole or to any of the inactive ingredients of **ADCO-METRONIDAZOLE** (see **COMPOSITION**).
- Patients with blood dyscrasias or with active disease of the central nervous system, or during pregnancy or lactation (see **HUMAN REPRODUCTION**).

WARNINGS AND SPECIAL PRECAUTIONS

Pseudomembranous colitis has been reported with the use of metronidazole.

Effects on ability to drive and use machines

ADCO-METRONIDAZOLE may affect the ability to drive a vehicle and use machines (see **SIDE EFFECTS**). Patients should ensure that they do not engage in driving or using machines until they know how **ADCO-METRONIDAZOLE** affects them.

INTERACTIONS

ADCO-METRONIDAZOLE tablets enhance the anticoagulant effect of warfarin. When given in conjunction with alcohol, **ADCO-METRONIDAZOLE** tablets may produce a disulfiram-like reaction.

HUMAN REPRODUCTION

There may be a temporary decrease in the total white cell count. **ADCO-METRONIDAZOLE** tablets should be avoided during pregnancy

DOSAGE AND DIRECTIONS FOR USE

Tablets should preferably be swallowed whole with half a glassful of water during or after meals.

UROGENITAL TRICHOMONIASIS

Both male and female should be treated.

200 mg tablet:

Adults:

10 tablets daily as a single dose for one day; or 1 tablet three times daily for seven days.

Children 7 to 10 years:

½ tablet three times daily for seven days.

Children 3 to 7 years:

½ tablet twice daily for seven days.

Children 1 to 3 years:

¼ tablet three times daily for seven days.

400 mg tablet:

Adults:

5 tablets daily as a single dose for one day; or 1 tablet morning and night for five days.

AMOEBIASIS

Susceptible patients

200 mg tablet:

Adults:

4 tablets three times daily for five to ten days.

Children 7 to 10 years:

2 tablets three times daily for five to ten days.

Children 3 to 7 years:

1 tablet four times daily for five to ten days.

Children 1 to 3 years:

1 tablet three times daily for five to ten days.

400 mg tablet:

Adults:

2 tablets three times a day for five to ten days; or 5 tablets daily as a single dose for three days

Less susceptible patients and in chronic amoebic hepatitis

200 mg tablet:

Adults:

2 tablets three times a day for five to ten days or 10 tablets daily as a single dose for two days.

Children 7 to 10 years:

1 tablet three times daily for five to ten days.

Children 3 to 7 years:

½ tablet four times daily for five to ten days.

Children 1 to 3 years:

½ tablet three times daily for five to ten days.

400 mg tablet:

Adults:

1 tablet three times a day for five to ten days; or 5 tablets daily as a single dose for two days.

AMOEBIC LIVER ABSCESS AND OTHER FORMS OF EXTRA-INTESTINAL AMOEBIASIS

200 mg tablet:

Adults:

2½ to 4 tablets three times a day for five to ten days; or 10 tablets daily as a single dose for two days.

Children 7 to 10 years:

1 tablet three times daily for five to ten days.

*Children 3 to 7 years***:**

½ tablet four times daily for five to ten days.

Children 1 to 3 years:

½ tablet three times daily for five to ten days.

400 mg tablet:

Adults:

1 to 2 tablets three times daily for five days; or 5 tablets daily as a single dose for two days.

SYMPTOMLESS PATIENTS WHO HAVE PASSED CYSTS

200 mg tablet:

Adults:

2 to 4 tablets three times a day for five to ten days.

Children 7 to 10 years:

1 to 2 tablets three times daily for five to ten days.

Children 3 to 7 years:

½ to 1 tablet four times daily for five to ten days.

Children 1 to 3 years:

½ to 1 tablet three times daily for five to ten days.

400 mg tablet:

Adults:

1 tablet three times daily for five to ten days.

GIARDIASIS

It may be necessary to repeat the treatment after two weeks of finishing the first course.

200 mg tablet:

Adults:

10 tablets daily as a single dose for three days.

Children 7 to 10 years:

5 tablets daily as a single dose for three days.

Children 3 to 7 years:

3 to 4 tablets daily as a single dose for three days.

Children 1 to 3 years:

2½ tablets daily as a single dose for three days.

400 mg tablet:

Adults:

5 tablets daily as a single dose for three days.

ULCERATIVE GINGIVITIS (VINCENT'S INFECTION)

200 mg tablet:

Adults:

1 tablet three times daily for three days.

Children 7 to 10 years:

½ tablet three times daily for three days.

Children 3 to 7 years:

½ tablet twice daily for three days.

Children 1 to 3 years:

¼ tablet three times daily for three days.

400 mg tablet:

Adults:

One tablet night and morning for three days.

ANAEROBIC INFECTIONS

ADCO-METRONIDAZOLE tablets may be given either alone or as a supplement to other antibacterial medicines.

Treatment:

Adults:

400 mg three times daily for seven days.

Children and infants:

7,5 mg/kg bodyweight three times daily, for seven days.

Prevention:

Adults:

2 g by mouth as a single dose on admission, then 200 mg three times daily for seven days after surgery.

SIDE EFFECTS

The side effects of **ADCO-METRONIDAZOLE** tablets include gastrointestinal discomfort, anorexia, nausea, coated tongue, dryness of the mouth and an unpleasant taste, headaches

and skin rashes and, less frequently, vertigo, depression, insomnia, drowsiness, urethral discomfort and darkening of the urine.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Early gastric lavage is recommended.

IDENTIFICATION

200 mg: Convex, white tablet with ADCO embossed on one side.

400 mg: Convex, white tablet with ADCO embossed on one side.

PRESENTATION

200 mg: White or beige coloured HDPE (high density polyethylene) securitainers of 21 and 250 tablets covered in white or beige coloured LDPE (low density polyethylene) or HDPE caps.

400 mg: White or beige coloured polypropylene or HDPE (high density polyethylene) securitainers of 10, 100 & 500 tablets covered in white or beige coloured LDPE (low density polyethylene) or HDPE caps.

Aluminium printed foil/PVC film blister packs of 5 and 100 tablets packed in outer carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

ADCO-METRONIDAZOLE 200 mg : R/20.2.6/187

ADCO-METRONIDAZOLE 400 mg : R/20.2.6/188

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

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Date of the most recently revised package insert: To be allocated.

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