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
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Private Bag X69
Bryanston, 2021
www.adcock.com

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of registration: 08/06/1984
Date of the most recently revised package insert: To be allocated

ADCO-METRONIDAZOLE 200 mg:
Namibia: 90/20.2.6/0088 NS2
Botswana: B9300225 S2

ADCO-METRONIDAZOLE 400 mg:
Namibia: 90/20.2.6/0089 NS2
Botswana: B9300230 S2

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SKEDULERINGSTATUS: **S4**

EIENDOMSNAAM EN DOSEERVORM
ADCO-METRONIDAZOLE 200 mg tablet
ADCO-METRONIDAZOLE 400 mg tablet

SAMESTELLING:
Elke **ADCO-METRONIDAZOLE 200 mg** tablet bevat metronidasool 200 mg
Elke **ADCO-METRONIDAZOLE 400 mg** tablet bevat metronidasool 400 mg
Bymiddels: Gelatien (graad 50), magnesium stearaat, mieliestysel, mikrokristallyne sellulose pH 101, natriumstyselglikolaat.

Suikervry

KATEGORIE EN KLAS:
A: 20.2.6 Middels teen protosoë

FARMAKOLOGIESE WERKING:
Metronidasool is 'n antiprotosoë middel wat effektief is teen *Trichomonas vaginalis, Entamoeba histolytica* en by giardiase. Metronidasool is nuttig vir die behandeling van infeksies veroorsaak deur verskeie anaërobiese bakterieë, veral *Bacteroides fragilis*.

INDIKASIES:
- Urogenitale trigomoniase
- Amebiase
- Giardiase
- Ulseratiewe tandvleisontsteking (Vincent-infeksie)
- Infeksies veroorsaak deur anaërobiese bakterieë veral Bacteroides fragilis. As 'n voorbehoedmiddel by postchirurgiese abdominale en bekken infeksies.

KONTRA-INDIKASIES:
- Hipersensitiwiteit teenoor metronidasool of enige van die onaktiewe bestanddele van **ADCO-METRONIDAZOLE** (sien **SAMESTELLING**).
- Pasiënte met bloeddiskrasieë of met 'n aktiewe siekte van die sentrale senuweestelsel, of gedurende swangerskap of laktasie (sien **MENSLIKE VOORTPLANTING**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Pseudomembraan kolitis is aangemeld met die gebruik van metronidasool.

Effek op die vermoë om te bestuur of masjinerie te gebruik:
ADCO-METRONIDAZOLE mag die vermoë om 'n voertuig te bestuur of masjinerie te gebruik beïnvloed (sien **NEWE-EFFEKTE**). Pasiënte moet seker maak dat hulle nie bestuur of masjinerie gebruik voordat hulle weet hoe **ADCO-METRONIDAZOLE** hulle affekteer nie.

INTERAKSIES:
ADCO-METRONIDAZOLE tablette verhoog die teenstollingseffek van warfarien.
Wanneer **ADCO-METRONIDAZOLE** tablette saam met alkohol geneem word kan 'n disulfiram-tipe reaksie ontwikkel.

MENSLIKE VOORTPLANTING:
Daar kan tydelike vermindering van die totale witbloedseltelling wees. Die gebruik van **ADCO-METRONIDAZOLE** tablette moet gedurende swangerskap vermy word.

DOSIS EN GEBRUIKSAANWYSINGS:
Die tablette moet verkieslik heel gesluk word met 'n halwe glas water tydens of na 'n maaltyd.

UROGENITALE TRIGOMONIASE:
Beide die man en vrou moet behandel word.

200 mg tablet:	
Volwassenes:	10 tablette daagliks as 'n enkeldosis vir een dag; of 1 tablet drie keer per dag vir sewe dae.
Kinders 7 tot 10 jaar:	½ tablet drie keer per dag vir sewe dae.
Kinders 3 tot 7 jaar:	½ tablet twee keer per dag vir sewe dae.
Kinders 1 tot 3 jaar:	¼ tablet drie keer per dag vir sewe dae.
400 mg tablet:	
Volwassenes:	5 tablette daagliks as 'n enkeldosis vir een dag; of 1 tablet soggens en saans vir vyf dae.

AMEBIASE:
Vatbare pasiënte:

200 mg tablet:	
Volwassenes:	4 tablette drie keer per dag vir vyf tot tien dae.
Kinders 7 tot 10 jaar:	2 tablette drie keer per dag vir vyf tot tien dae.
Kinders 3 tot 7 jaar:	1 tablet vier keer per dag vir vyf tot tien dae.
Kinders 1 tot 3 jaar:	1 tablet drie keer per dag vir vyf tot tien dae.
400 mg tablet:	
Volwassenes:	2 tablette drie keer per dag vir vyf tot tien dae; of 5 tablette daagliks as 'n enkeldosis vir drie dae.

Minder vatbare pasiënte en by pasiënte met chroniese amebiese lewerontsteking:

200 mg tablet:	
Volwassenes:	2 tablette drie keer per dag vir vyf tot tien dae of 10 tablette daagliks as 'n enkeldosis vir twee dae.
Kinders 7 tot 10 jaar:	1 tablet drie keer per dag vir vyf tot tien dae.
Kinders 3 tot 7 jaar:	½ tablet vier keer per dag vir vyf tot tien dae.
Kinders 1 tot 3 jaar:	½ tablet drie keer per dag vir vyf tot tien dae.
400 mg tablet:	
Volwassenes:	1 tablet drie keer per dag vir vyf tot tien dae; of 5 tablette daagliks as 'n enkeldosis vir twee dae.

AMEBIESE LEWERABSES EN ANDER VORMS VAN BUITE-INGEWANDSAMEBIASE:

200 mg tablet:	
Volwassenes:	2½ tot 4 tablette drie keer per dag vir vyf dae; of 10 tablette daagliks as 'n enkeldosis vir twee dae.
Kinders 7 tot 10 jaar:	1 tablet drie keer per dag vir vyf tot tien dae.
Kinders 3 tot 7 jaar:	½ tablet vier keer per dag vir vyf tot tien dae.
Kinders 1 tot 3 jaar:	½ tablet drie keer per dag vir vyf tot tien dae.
400 mg tablet:	
Volwassenes:	1 tot 2 tablette drie keer per dag vir vyf dae; of 5 tablette daagliks as 'n enkeldosis vir twee dae.

SIMPTOOMLOSE PASIËNTE MET SISTUITSKEIDING:

200 mg tablet:	
Volwassenes:	2 tot 4 tablette drie keer per dag vir vyf tot tien dae.
Kinders 7 tot 10 jaar:	1 tot 2 tablette drie keer per dag vir vyf tot tien dae.
Kinders 3 tot 7 jaar:	½ tot 1 tablet vier keer per dag vir vyf tot tien dae.
Kinders 1 tot 3 jaar:	½ tot 1 tablet drie keer per dag vir vyf tot tien dae.
400 mg tablet:	
Volwassenes:	1 tablet drie keer per dag vir vyf tot tien dae.

GIARDIASE:
Dit mag nodig wees om die behandeling twee weke na afloop van die eerste behandelingsreeks te herhaal.

200 mg tablet:	
Volwassenes:	10 tablette daagliks as 'n enkeldosis vir drie dae.
Kinders 7 tot 10 jaar:	5 tablette daagliks as 'n enkeldosis vir drie dae.
Kinders 3 tot 7 jaar:	3 tot 4 tablette daagliks as 'n enkeldosis vir drie dae.
Kinders 1 tot 3 jaar:	2½ tablette daagliks as 'n enkeldosis vir drie dae.
400 mg tablet:	
Volwassenes:	5 tablette daagliks as 'n enkeldosis vir drie dae.

ULSERERENDE TANDVLEISONTSTEKING (VINCENT-INFEKSIE):

200 mg tablet:	
Volwassenes:	1 tablet drie keer per dag vir drie dae.
Kinders 7 tot 10 jaar:	½ tablet drie keer per dag vir drie dae.
Kinders 3 tot 7 jaar:	½ tablet twee keer per dag vir drie dae.
Kinders 1 tot 3 jaar:	¼ tablet drie keer per dag vir drie dae.
400 mg tablet:	
Volwassenes:	Een tablet saans en soggens vir drie dae.

ANAËROBIESE INFEKSIES:
ADCO-METRONIDAZOLE tablette kan of alleen of as 'n aanvulling met ander antibakteriese middels gegee word.

Behandeling:	
Volwassenes:	400 mg drie keer per dag vir sewe dae.
Kinders en kleuters:	7,5 mg/kg liggaamsmassa drie keer per dag, vir sewe dae.
Voorkoming:	
Volwassenes:	2 g mondelings as 'n enkeldosis met opname, daarna 200 mg drie keer per dag vir sewe dae na chirurgie.

NEWE-EFFEKTE:
Die newe-effekte van **ADCO-METRONIDAZOLE** tablette sluit maagderm-ongemak, anoreksie, mislikheid, aangepakte tong, droë mond en 'n onaangename smaak, hoofpyne en veluitslag in. Newe-effekte wat nie so dikwels voorkom nie sluit vertigo, depressie, slaaploosheid, lomerigheid, urienbuis-ongemak en verdonkering van die uriene in.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Vroegtydige maagspoeling word aanbeveel.

IDENTIFIKASIE:
200 mg: Konvekse, wit tablette met ADCO op een kant gedruk.
400 mg: Konvekse, wit tablette met ADCO op een kant gedruk.

AANBIEDING:
200 mg: Wit of roomkleurige HDPE (hoëdigtheid poliëtileen) houers met 21 of 250 tablette, bedek met wit of roomkleurige LDPE (laedigtheid poliëtileen) of HDPE doppe.
400 mg: Wit of roomkleurige polipropileen of HDPE (hoëdigtheid poliëtileen) securitainers met 10, 100 of 500 tablette, bedek met wit of roomkleurige LDPE (laedigtheid poliëtileen) of HDPE doppe.
Aluminium gedrukte foelie/PVC film stulpstroke met 5 of 100 tablette verpak in 'n karton boksie.

BERGINGSAANWYSINGS:
Bêre teen of benede 25 °C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
ADCO-METRONIDAZOLE 200 mg: R/20.2.6/187
ADCO-METRONIDAZOLE 400 mg: R/20.2.6/188

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Adcock Ingram Limited
New Road 1
Erand Gardens
Midrand, 1685
Privaatsak X69
Bryanston, 2021
www.adcock.com

adcock ingram

DATUM VAN PUBLIKASIE VAN HIERDIE PROFESSIONELE INLIGTING:
Datum van registrasie: 08/06/1984
Datum van voubiljet wat mees onlangs opdateer is: Moet aangewys word

ADCO-METRONIDAZOLE 200 mg:
Namibië: 90/20.2.6/0088 NS2
Botswana: B9300225 S2

ADCO-METRONIDAZOLE 400 mg:
Namibië: 90/20.2.6/0089 NS2
Botswana: B9300230 S2

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