Amodis®

Metronidazole

COMPOSITION

Amodis® 400 Tablet : Each film coated tablet contains Metronidazole BP 400 mg.

Amodis® 500 Tablet : Each film coated tablet contains Metronidazole BP 500 mg.

Amodis® Suspension: Each 5 ml contains Metronidazole 200 mg as Metronidazole Benzoate BP.

PHARMACOLOGY

Amodis® (Metronidazole), a nitroimidazole has an extremely broad spectrum antiprotozoal and antimicrobial activities, with high activity against anaerobic bacteria and protozoa. **Amodis®** (Metronidazole) is usually completely and rapidly absorbed after oral administration. The half-life in plasma is about 8 hours. About 10% of the drug is bound to plasma proteins. **Amodis®** (Metronidazole) penetrates well into body tissues and fluids. The liver is the main site of metabolism. Both unchanged Metronidazole and metabolites are excreted in various proportions in the urine after oral administration.

INDICATION

● All forms of amoebiasis (intestinal and extra-intestinal disease including liver abscess and that of symptomless cyst passers) ● Trichomoniasis ● Giardiasis ●Bacterial vaginosis ●Acute ulcerative gingivitis ●Anaerobic infections including septicaemia, bacteraemia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis etc. ● Anaerobically-infected leg ulcers and pressure sores ● Acute dental infections (e.g. acute pericoronitis and acute apical infections) ● Surgical prophylaxis (prevention of postoperative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci ● Chronic symptomatic peptic ulcer disease (as an agent of triple therapy to eradicate *H. pylori*-the most important etiological factor of peptic ulcer)

ADVERSE REACTION

Metalic taste, furred tongue, nausea, vomiting, diarrhoea, drowsiness, rashes and mild reversible leucopenia may be observed during treatment.

DRUG INTERACTION

Metronidazole interacts with warfarin, phenytoin, phenobarbitone, fluorouracil, disulfiram, lithium, cimetidine etc.

PREGNANCY & LACTATION

Not recommended during first & later trimesters. Breast feeding should be delayed until 48 hours after discontinuing metronidazole in the mother.

STORAGE CONDITION

Tablet: Store below 30°C . Protect from light . Keep out of the reach of children.

Suspension: Store below 25°C . Protect from light . Keep out of the reach of children.

DOSAGE & ADMINISTRATION

If not otherwise prescribed by the physician the following dosage schedule may be followed:

Indication	Duration of dosage in days	Adult & Children over 10 years	Children		
			7-10 years	3-7 years	1-3 years
Trichomoniasis	7	200 mg t.i.d. or 400 mg b.i.d.	100 mg t.i.d.	100 mg b.i.d.	50 mg t.i.d.
	2	800 mg in the morning and 1.2 gm at night	----	----	----
	1	2.0 gm as a single dose	----	----	----
Invasive intestinal amoebiasis	5	800 mg t.i.d.	400 mg t.i.d.	200 mg q.i.d.	200 mg t.i.d.
Extra intestinal amoebiasis (including liver abscess) and symptomless amoebic cyst passers	5-10	400-800 mg t.i.d.	200-400 mg t.i.d.	100-200 mg q.i.d.	100-200 mg t.i.d.
Giardiasis	3	2.0 gm once daily	1.0 gm once daily	600-800 mg once daily	500 mg once daily
Acute ulcerative gingivitis	3	200 mg t.i.d.	100 mg t.i.d.	100 mg b.i.d.	50 mg t.i.d.
Acute dental infections	3-7	200 mg t.i.d.	----	----	----
Bacterial vaginosis	5-7	400-500 mg twice daily	----	----	----
	1	2.0 gm as a single dose	----	----	----
Leg ulcers and pressure sores	7	400 mg t.i.d.	----	----	----
Anaerobic infections	7	Either 400 mg every 8hours or 500 mg every 8 hours	7.5 mg/kg t.i.d.	7.5 mg/kg t.i.d.	7.5 mg/kg t.i.d.
Surgical prophylaxis		400–500 mg 2 hours before surgery; up to 3 further doses of 400–500 mg may be given every 8 hours for high-risk procedures	7.5 mg/kg t.i.d.	7.5 mg/kg t.i.d.	7.5 mg/kg t.i.d.

HOW SUPPLIED

Amodis® 400 Tablet : Box containing 200 tablets in blister pack

Amodis® 500 Tablet : Box containing 100 tablets in blister pack

Amodis® Suspension : Each PET bottle contains 60 ml suspension with measuring cup

Manufactured for:

SQUARE
PHARMACEUTICALS LTD.
Bangladesh