Only for the use of Medical Professionals

Amotrex®

Metronidazole

Presentation

Amotrex® 200mg Tablets: Each tablet contains Metronidazole BP 200mg.
Amotrex® 400mg Tablets: Each tablet contains Metronidazole BP 400mg.
Amotrex® DS 800mg Tablets: Each tablet contains Metronidazole BP 800mg.
Amotrex® Suspension: Each 5ml contains Metronidazole 200mg as Benzoyl BP.

Uses

Amotrex® is active against a wide range of pathogenic microorganisms notably Bacteroides, Fusobacteria, Clostridia, Eubacteria and Anaerobic cocci. Amotrex¨ is also active against Trichomonas, Entamoeba hystolytica, Giardia lamblia and Balantidium coli.
It is indicated in:

1. The prevention of post-operative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci.
2. The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis and post-operative wound infections from which susceptible pathogenic anaerobes have been isolated.
3. Urogenital trichomoniasis in the female (trichomonal vaginitis) and in the male.
4. Bacterial vaginitis.
5. All forms of amoebiasis (intestinal or extra intestinal diseases and that of symptomless cyst passers).
6. Giardiasis.
7. Acute ulcerative gingivitis.
8. Anaerobically infected leg ulcers and pressure sores.
9. Acute dental infections (eg acute pericoronitis and acute apical infections).

Metronidazole is rapidly and almost completely absorbed on administration. Peak plasma concentration occurs after 20 min to 3 hours. The elimination half-life of Metronidazole is 7-8 hours. Metronidazole can be used in chronic ranal failure; it is rapidly removed by dialysis. Metronidazole is excreted in milk but the intake of a suckling infant of a mother receiving normal dosage would be considerably less than the therapeutic dosage for infants.

Dosage and administration□

Amotrex® Tablet should be swalloed with water (NOT CHEWED). It is recommended that the tablets should be taken during or after meal.
Amotrex® Suspension should be taken at least one hour before a meal. Other antibiotics may be used concurrently.
Anaerobic infections:The duration of a course of Amotrex ® treatment is about 7 days but it will depend upon the seriousness of the patients condition as assessed clinically and bacteriologically.

A. Prophylaxis against anaerobic infection, chiefly in the context abdominal (especially colorectal) and gynaecological surgery:
Oral : 400mg 8 hourly for 3-4 days and continued post operatively.

B. Treatment of established anaerobic infections:
Oral : 800mg followed by 400mg 8 hourly. □Children: 7.5mg/kg 8 hourly.

C. The dosage for the treatment of protozoal and other infection are given in the table 1.
Elderly : Amotrex® is well-tolerated by the elderly, but a pharmacokinetic study suggests cautious use of high dosage regimens on this age group.

Contra-indications, warnings, etc.
Contra-indications: Known hypersensitivity to Metronidazole.

Use in pregnancy: There is inadequate of the safety to Metronidazole in pregnancy but it has been in use for many years without apparent ill consequences. Nevertheless, Amotrex® like other medicines should not be given during pregnancy or during lactation unless the physician considers it essential. In these circumstances the short, high dosage regimens are not recommended.

Precautions: There is a possibility that after Trichomonas vaginalis has been eliminated, gonococcal infection might persist. The elimination half-life of Metronidazole remains unchanged in the presence of renal failure. The dosage of Metronidazole, therefore, needs no reduction. Such patients, however, retain the metabolites of Metronidazole. The clinical significance is not known at present. In patients undergoing haemodialysis Metronidazole and metabolites are efficiently removed during an eight hour period of dialysis. Metronidazole should therefore, be administered immediately after haemodialysis.

Table 1: Dose is given in terms of Metronidazole or Mtronidazole equivalent

	Duration of dosage in days	Adults and children over 10 years	Children		
			7 to 10 Years	3 to 7 Years	1 to 3 Years
Urogenital trichomoniasis: where reinfection is likely the consort should receive similar course of treatment concurrently	7	200mg three times daily			
	Or 2	800mg in the morning and 1200mg in the evening			
	Or 1	2.0g as a single dosage			
Bacterial Vaginitis	7	400mg twice daily			
	Or 1	2.0g as a single dosage			

Amoebiasis a) Invasive intestinal disease in susceptible subjects b) Intestinal disease in less susceptible subjects and chronic amoebic hepatitis c) Amoebic liver abscess also other forms of extra - intestinal amoebiasis d) Symptomless cyst passers	5	800mg three times daily	400mg three times daily	200mg Four times daily	200mg three times daily
	5-10	400mg three times daily	200mg three times daily	100mg Four times daily	100mg three times daily
	5	400mg three times daily	200mg three times daily	100mg Four times daily	100mg three times daily
	5-10	400-800mg three times daily	200-400mg three times daily	100-200mg Four times daily	100-200mg three times daily
Giardiasis	3	2.0g once daily	1.0g once daily	600-800mg once daily	500mg once daily
Acute ulcerative gingivitis	3	200mg three times daily	100mg three times daily	100mg twice daily	50mg three times daily
Acute dental infections	3-7	200mg three times daily			
Leg ulcers and pressure sores	7	400mg three times daily			
Anaerobic infections a) Prophylaxis	3-4	400mg three times daily			
b) Treatment	7	400mg three times daily			

Caution in patients with hepatic impairment : Patients should be advised not to take alcohol during Metronidazole therapy because of the possibility of a disulphiram-like

reaction. In case of advanced hepatic insufficiency, dosage should be adjusted to avoid accumulation of Metronidazole in the plasma.

Drug interactions : Some potentiation of anticoagulant therapy has been reported when Metronidazole has been used with the warfarin type oral anticoagulants. Dosage of the latter may require reduction. Prothrombin times should be monitored. There is no interaction with heparin.
Patients receiving phenobarbitone metabolise Metronidazole at a much greater rate than normally, reducing the half-life to approximately 3 hours.

Warnings and adverse effects : Serious adverse reactions occur very rarely with standard recommended regimens. Unpleasant tastes in the mouth, furred tongue, nausea, vomiting, gastro-intestinal disturbances and urticaria and angioedema occur occasionally. Anaphylaxis may occur rarely. Drowsiness, dizziness, headache, ataxia, skin rashes, pruritus, darkening of the urine (due to Metronidazole metabolites) have been reported but very rarely. During intensive and/or prolonged Metronidazole therapy a few instances of peripheral neuropathy or transient epileptiform seizures have been reported but in most cases neuropathy disappeared after treatment was stopped or when dosage was reduced. A moderate leucopenia has been reported in some patients but the white cell count has always returned to normal before or after treatment has been completed.

Treatment of overdosage : There is no specific treatment for gross overdosage of Amotrex®.

Pharmaceutical precautions
Amotrex® 200mg, 400mg Tablets and Suspension : Store at room temperature and dry place, protected from light.
Amotrex® DS 800mg Tablets : Store in a cool dry place. Protect from light.

Package quantities
Amotrex® 200mg Tablets : Carton of 100 tablets in blister.
Amotrex® 400mg Tablets : Carton of 100 tablets in blister.
Amotrex® DS 800mg Tablets: Carton of 100 tablets in blister.
Amotrex® Suspension : Bottle of 60ml.

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