1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of medicinal product

METRONIDAZOLE TABLETS BP 200MG

2. Composition:

Each uncoated tablet contains:
Metronidazole BP 200MG
Excipients…… Q.S.

3. Pharmaceutical Form:

Solid Oral

4. Clinical Particulars

4.1 Indication

It is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or are suspected to be the cause.

It is active against a wide range of pathogenic micro- organisms, notably species of Bacteroides, Fusobacteria, Clostridia, Eubacteria, anaerobic cocci and Gardnerella vaginalis.

It is also active against Trichomonas vaginalis and other species of trichomonads, Entamoeba histolytica, Giardia lamblia, Balantidium coli and the causative organisms of acute ulcerative gingivitis.

4.2 Posology and Administration

Anaerobic infections: The duration of a course of Metronidazole Tablets 200mg treatment is about 7 days but it will depend upon the seriousness of the patient's condition as assessed clinically and bacteriologically.

Prophylaxis against anaerobic infection: Chiefly in the context of abdominal (especially colorectal) and gynaecological surgery.

Adults: 400mg 8-hourly during 24 hours immediately preceding operation followed by postoperative intravenous or rectal administration until the patient is able to take the tablets.

Children: < 12 years: 20-30mg/kg as a single dose given 1-2 hours before surgery. Newborns with a gestation age of < 40 weeks: 10mg/kg body weight as a single dose before operation.

4.3 Contraindication

Hypersensitivity to nitroimidazoles, metronidazole or any of the excipients.

4.4 Special Warning & precautions for use

Metronidazole should be used with caution in patients with active or chronic severe peripheral and central nervous system disease due to the risk of neurological aggravation.
The possibility that an accompanying gonococcal infection might persist in a symptomatic state after Trichomonas vaginalis has been eliminated should be borne in mind.
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 of this 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 re- administered immediately after haemodialysis.

4.5 Interaction with other medicinal products and other forms of interaction

Patients should be advised not to take alcohol during therapy and for at least 48 hours afterwards because of the possibility of a disulfiram-like (antabuse effect) reaction.

Concomitant administration of disulfiram has led to acute psychosis and confusional states.

The effects of warfarin type oral anticoagulants may be potentiated by metronidazole. The dose of warfarin type oral anticoagulants may require reducing. Prothrombin times should be monitored. There is no interaction with heparin.

Lithium retention accompanied by evidence of possible renal damage has been reported in patients treated simultaneously with lithium and metronidazole. Lithium treatment should be tapered or withdrawn before administering metronidazole. Plasma concentrations of lithium, creatinine and electrolytes should be monitored in patients under treatment with lithium while they receive metronidazole.

Phenobarbital and Phenytoin causes increased metabolism of metronidazole, reducing the half life to about three hours.

Metabolism of metronidazole is accelerated by primidone.

Metronidazole inhibits the metabolism of phenytoin (increased plasma concentration).

Metronidazole reduces the clearance of 5 fluorouracil and can therefore result in increased toxicity of 5 fluorouracil.

Patients receiving ciclosporin are at risk of elevated ciclosporin serum levels. Serum ciclosporin and serum creatinine should be closely monitored when co-administration is necessary.

Plasma levels of busulfan may be increased by metronidazole which may lead to severe busulfan toxicity.

Metronidazole possibly reduces bioavailability of mycophenolate. The metabolism of

metronidazole is inhibited by cimetidine.

Antibacterials that do not induce liver enzymes possibly reduce the contraceptive effect of oestrogens.

4.6 Fertility, Pregnancy and lactation
Metronidazole should not be given in these circumstances unless it is considered essential by the physician. If it is used, then short-term high dosage therapy is not recommended.

4.7 Effects on ability to drive and use machines
Patients should be warned about the potential for drowsiness, dizziness, confusion, hallucinations, convulsions or transient visual disorders, and advised not to drive or operate machinery if these symptoms occur

4.8 Undesirable effects
Common adverse effects are anaphylactic reaction, hypersensitivity, hyperkalaemia, depression, hallucination, nausea, diarrhea etc.

4.9 Overdose
Single oral doses of metronidazole, up to 12g have been reported in suicide attempts and accidental overdoses. Symptoms are limited to vomiting, ataxia and slight disorientation. There is no specific treatment for gross over dosage of metronidazole. In cases of suspected massive overdose, symptomatic and supportive treatment should be instituted.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antibacterials for systemic use, ATC code: J01X D01

Metronidazole is an antimicrobial agent acting against a wide range of anaerobic bacteria and protozoa including Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia.

5.2 Pharmacokinetic properties
Metronidazole is rapidly absorbed from the gastro-intestinal tract. Peak plasma concentrations occur between twenty minutes and three hours.
The elimination half-life is 8.5±2.9 hours. Metronidazole can be used in chronic renal failure; it is rapidly removed from the plasma 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.

5.3 Preclinical Safety Data; Not Applicable

6. Shelf Life
36 months

7. Special precaution for Storage

Do not store above 30°C.

8. Nature and contents of container
Tablets are available in blister pack packed in carton along with insert.

9. Marketing Holder

First Vadis Pharmaceutical Industries Limited

Plot IN/2 Phase 2 Extension, Emene Industrial Layout Enugu state

10. Manufacturer

First Vadis Pharmaceutical Industries Limited

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