FASIGYN® TABLETS
Tinidazole

SCHEDULING STATUS:
Schedule 4

PROPRIETARY NAME:
FASIGYN® 500 mg Oral Film Coated Tablets

COMPOSITION:
FASIGYN (tinidazole) is a derivative of the substituted imidazole group of compounds. Each 500 mg FASIGYN tablet contains 500 mg tinidazole base. FASIGYN tablets contain the following inert ingredients: alginic acid, cellulose, corn starch, magnesium stearate, sodium lauryl sulphate and are film coated with hydroxypropylmethylcellulose, propylene glycol and titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION:
A.20.2.6 Medicines against protozoa

PHARMACOLOGICAL ACTION:
FASIGYN is an agent for the treatment of infections due to the protozoa Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia; and for the prophylaxis and treatment of infections due to anaerobic bacteria. In vitro FASIGYN has been shown to be effective against Bacteroides fragilis, other Bacteroides species, Fusobacterium species, peptococci, peptostreptococci, clostridia, eubacteria and veillonella.
INDICATIONS:

FASIGYN (tinidazole) is an agent for the treatment of infections due to the protozoa *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia lamblia*. FASIGYN (tinidazole) is specifically indicated for the oral treatment of:

(a) Urogenital trichomoniasis in both male and female patients. When infection with *Trichomonas vaginalis* is confirmed, simultaneous treatment of the consort is recommended.

(b) Giardiasis.

(c) Intestinal amoebiasis and amoebic involvement of the liver.

FASIGYN (tinidazole) has been successfully used in:

(a) The prevention of postoperative infections caused by anaerobic bacteria, especially infections after colonic, gastro-intestinal and gynaecological surgery.

(b) The treatment of infections due to strains of anaerobic bacteria such as susceptible strains of *Bacteroides* species, *Fusobacterium* species, peptococci, peptostreptococci, *clostridia*, *eubacteria* and *veillonella*.

(c) The treatment of acute ulcerative gingivitis.

CONTRA-INDICATIONS:

FASIGYN (tinidazole) is contra-indicated in patients having, or with a history of, blood dyscrasia although no persistent haematological abnormalities have been noted in clinical or animal studies.

FASIGYN (tinidazole) should be avoided in patients with organic neurological disorders.

Use of FASIGYN is contra-indicated during pregnancy and in nursing mothers.

FASIGYN (tinidazole) should not be administered to patients with a known hypersensitivity to the drug or to any of its components.

DOSAGE AND DIRECTIONS FOR USE:

It is recommended that oral FASIGYN (tinidazole) be taken during or after a meal.
(a) **Urogenital Trichomoniasis**

   (1) Adults - preferred regimen - 2 g orally as a single stat dose.
   
   (2) Children - 50 mg - 75 mg per kg of body mass given as a single dose. It may be necessary to repeat this dose once in some cases.

(b) **Giardiasis**

   (1) Adults - 2 g orally as a single stat dose.
   
   (2) Children - 50 mg - 75 mg per kg of body mass given as a single dose. It may be necessary to repeat this dose once in some cases.

(c) **Intestinal Amoebiasis**

   (1) Adults - 2 g orally as a single daily dose for 3 days.
   
   (2) Children - 60 mg per kg of body mass given as a single daily dose on each of 3 consecutive days.

(d) **Amoebic involvement of the liver:**

   (1) Adults - total dosage for this indication varies from 4.5 g to 12 g, depending on the virulence of the *Entamoeba histolytica*. Treatment should be initiated with 1.5 to 2 g orally as a single dose for 3 days. In the occasional instance where a 3 day course is ineffective, treatment may be continued for up to a total of 6 days.
   
   (2) Children - 60 mg per kg of body mass is given as a single daily dose on each of 5 successive days.

   In amoebic involvement of the liver the aspiration of pus may be required in addition to therapy with FASIGYN (tinidazole).

(e) **Prevention of postoperative infections:**

   Adults - a single oral dose of 2 g approximately 12 hours before surgery.

(f) **Treatment of anaerobic infections:**

   Adults - an initial dose of 2 g the first day, followed by 1 g daily, given as a single oral dose or as 500 mg twice daily. Treatment for 5 - 6 days will generally be adequate, but clinical judgement must determine the duration of therapy, particularly when eradication of infection from certain sites may be
Regular clinical and laboratory observation is advised if it is considered necessary to continue therapy for more than 7 days.

(g) Acute ulcerative gingivitis:
Adults - a single oral dose of 2 g.

Dosage recommendations for children below the age of 12 in the prophylaxis and treatment of anaerobic infections have not yet been established.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Gastro-intestinal side effects include nausea, vomiting, anorexia, diarrhoea, metallic taste and abdominal pain.

FASIGYN may produce transient leucopenia. Other less frequently reported side effects are headache, tiredness, furry tongue and dark urine.

Hypersensitivity reactions, occasionally severe, may occur less frequently in the form of skin rash, pruritis, urticaria and angioneurotic oedema.

Alcoholic beverages should be avoided during FASIGYN therapy because of the possibility of a disulfiram-like reaction (flushing, abdominal cramps, vomiting, tachycardia). Alcohol should be avoided until 72 hours after discontinuing FASIGYN.

Drugs of similar chemical structure, including FASIGYN have been associated with various neurological disturbances such as dizziness, vertigo, ataxia, peripheral neuropathy (paresthesia, sensory disturbances, hypesthesia) and rarely, convulsions.

If any abnormal neurological signs develop during FASIGYN therapy, the drug should be discontinued.

Effects on Ability to Drive and Use Machines
The effect of tinidazole on the ability to drive or operate heavy machinery has not been studied.
Interactions

Alcohol - alcohol may produce a disulfiram-like reaction.

Usage in Pregnancy
Tinidazole crosses the placental barrier.

Usage in Nursing Mothers
Tinidazole is excreted in breast milk. Tinidazole may continue to appear in breast milk for more than 72 hours after administration. Women should not nurse until at least three days after having discontinued taking FASIGYN.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
There is no specific antidote for treatment of overdosage with tinidazole. Treatment is symptomatic and supportive. Gastric lavage may be useful. Tinidazole is easily dialyzable.

IDENTIFICATION:
FASIGYN 500 mg oral film coated tablets are white, round, biconvex tablets having a smooth uniformly coloured finish. The tablets are engraved “FAS 500” on one side.

PRESENTATION:
FASIGYN 500 mg oral film coated tablets packs of 4’s.

STORAGE INSTRUCTIONS:
Store below 30 °C. Keep out of reach of children.

REGISTRATION NUMBER:
F/20.2.6/183
Pfizer Laboratories (Pty) Ltd
FASIGYN 500 mg Tablets
Approved PI – 14 May 2004

NAME OF APPLICANT:
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