1. NAME OF THE MEDICINAL PRODUCT

Albegyl Tablet 200mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Metronidazole BP.....200mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Yellow round tablet embossed with "ALBEN" on one side and plain on the other side.

4. Clinical Particulars

4.1 Therapeutic indications

Albegyl is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or are suspected to be the cause. Albegyl 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, Entamoeba histolytica, Giardia lamblia and Balantidium coli. It is indicated in

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

4.2 Posology and method of administration

For oral route of administration. All dosages are given in terms of metronidazole or metronidazole equivalent. Albegyl tablets should be swallowed with water (not chewed). It is recommended that the tablets be taken during or after a meal.

Anaerobic Infections: The duration of a course of Albegyl 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) an gynaecological surgery.

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

Children and infants: 7.5 mg/kg 8 hourly

Treatment of established anaerobic infection:

Adults: 800 mg followed by 400 mg 8 hourly

Children and infants: 7.5 mg/kg 8 hourly

4.3 Contraindications
Known hypersensitivity to metronidazole.

4.4 Special warnings and precaution for use

Regular clinical and laboratory monitoring are advised if administration of Albegyl for more than 10 days is considered to be necessary. There is a possibility that after Trichomonas vaginalis has been eliminated a 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 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. No routine adjustment in the dosage of Albegyl need be made in patients with renal failure undergoing intermittent peritoneal dialysis (IPD) or continuous ambulatory peritoneal dialysis (CAPD). Metronidazole is mainly metabolised by hepatic oxidation. Substantial impairment of metronidazole clearance may occur in the presence of advanced hepatic insufficiency. Cases of severe hepatotoxicity/acute hepatic failure, including cases with a fatal outcome with very rapid onset after treatment initiation, in patients with Cockayne syndrome have been reported with products containing metronidazole for systemic use. In this population, metronidazole should be therefore be used after careful benefit-risk assessment and only if no alternative treatment is available. Liver functions tests must be performed just prior to the start of therapy, throughout and after end of treatment until liver function is within normal ranges, or until the baseline values are reached. If the liver function tests become markedly elevated during treatment, the drug should be discontinued. Patients with Cockayne syndrome should be advised to immediately report any symptoms of potential liver injury to their physician and stop taking metronidazole. Cases of severe bullous skin reactions such as Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or acute generalized exanthematous pustulosis (AGEP) have been reported with metronidazole. If symptoms or signs of SJS, TEN or AGEP are present, treatment must be immediately discontinued Significant cumulation may occur in patients with hepatic encephalopathy and the resulting high plasma concentrations of metronidazole may contribute to the symptoms of the encephalopathy. Albegyl should therefore, be administered with caution to patients with hepatic encephalopathy. The daily dosage should be reduced to one third and may be administered once daily.

4.5 Interactions with other medicinal products and other forms of interaction
Patients should be advised not to take alcohol during metronidazole therapy and for at least 48 hours afterwards because of the possibility of a disulfiram-like (antabuse effect) reaction. 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 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. Patients receiving phenobarbitone metabolise metronidazole at a much greater rate than normally, reducing the half-life to approximately 3 hours. Metronidazole reduces the clearance of 5-fluorouracil and can

therefore result in increased toxicity of 5-fluorouracil. Patients receiving cyclosporin are at risk of elevated cyclosporin serum levels. Serum cyclosporin and serum creatinine should be closely monitored when coadministration is necessary. Plasma levels of busulfan may be increased by metronidazole which may lead to severe busulfan toxicity

4.6 Pregnancy and Lactation

There is inadequate evidence of the safety of metronidazole in pregnancy but it has been in wide use for many years without apparent ill consequence. Nevertheless Albegyl, 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.

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

The frequency of adverse events listed below is defined using the following convention:

very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).
Serious adverse reactions occur rarely with standard recommended regimens. Clinicians who contemplate continuous therapy for the relief of chronic conditions, for periods longer than those recommended, are advised to consider the possible therapeutic benefit against the risk of peripheral neuropathy.
Blood and lymphatic system disorders:
Very rare: agranulocytosis, neutropenia, thrombocytopenia, pancytopenia
Not known: leucopenia.
Immune system disorders: Rare: anaphylaxis Not known: angiodema, urticaria, fever.
Metabolism and nutrition disorders:
Not known: anorexia.
Psychiatric disorders:
Very rare: psychotic disorders, including confusion and hallucinations.
Not known: depressed mood
Nervous system disorders:
Very rare:

- encephalopathy (eg. confusion, fever, headache, hallucinations, paralysis,• light sensitivity, disturbances in sight and movement, stiff neck) and subacute cerebellar syndrome (eg. ataxia, dysathria, gait impairment, nystagmus and tremor) which may resolve on discontinuation of the drug.
- drowsiness, dizziness, convulsions, headaches
- Not known:
- during intensive and/or prolonged metronidazole therapy, peripheral sensory• neuropathy or transient epileptiform seizures have been reported. In most cases neuropathy disappeared after treatment was stopped or when dosage was reduced.

- aseptic meningitis
- Eye disorders:

  Very rare: vision disorders such as diplopia and myopia, which, in most cases, is transient. Not Known: optic neuropathy/neuritis Ear and labyrinth disorders Not known: hearing impaired/hearing loss (including sensorineural), tinnitus

Gastrointestinal disorders:
Not known: taste disorders, oral mucositis, tongue discolouration/furred tongue (e.g. due to fungal overgrowth), nausea, vomiting, gastro-intestinal disturbances such as epigastric pain and diarrhoea.
Hepatobiliary disorders:
Very rare:
increase in liver enzymes (AST, ALT, alkaline phosphatase), cholestatic or• mixed hepatitis, and hepatocellular injury, sometimes with jaundice and pancreatitis which is reversible on drug withdrawal.
cases of liver failure requiring liver transplant have been reported in patients• treated with metronidazole in combination with other antibiotic drugs.
Skin and subcutaneous tissue disorders:
Very rare: skin rashes, pustular eruptions, pruritis, flushing, fixed drug eruption, acute generalized exanthematous pustulosis
Not known: erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.
Musculoskeletal, connective tissue and bone disorders:
Very rare: myalgia, arthralgia.
Renal and urinary disorders:
Very rare: darkening of urine (due to metronidazole metabolite).

4.9 Overdose

There is no specific treatment for gross overdosage of Albegyl.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Metronidazole has antiprotozoal and antibacterial actions and is effective against Trichomonas vaginalis and other protozoa including Entamoeba histolytica and Gardia lambila and against anaerobic bacteria.

5.2 Pharmacokinetic properties

Metronidazole is rapidly and almost completely absorbed on administration of Albegyl tablets; peak plasma concentrations occur after 20 min to 3 hours. The half life of metronidazole 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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

- Starch
- Gelatin
- Sodium Propyl Paraben
- Lactose
- Magnesium stearate
- Tartrazine Yellow
- Purified Water

6.2 Incompactibilities

- None relevant known.

6.3 Shelf life

- 36 Months

6.4 Special precautions for storage

- Do not store above 30°C
- Store in a cool dry place protected from light and out of reach of children.

6.5 Nature and contents of container<and special equipment for use, administration or implantation>

- 10 tablet blisters and 10 such blisters in a monocarton.
- Tin of 1000 tablets.

6.6 Special precautions for disposal<and other handling>

- None.

7. Applicant/Manufacturer

- Name: Alben Healthcare Industries Limited.
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