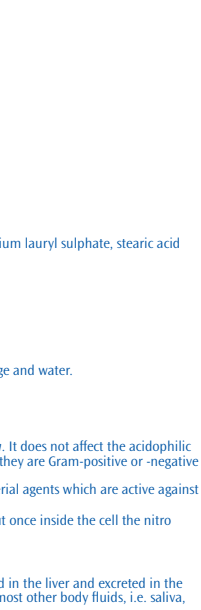


Flagyl[®]

Metronidazole



SCHEDULING STATUS: S2
PROPRIETARY NAME (AND DOSAGE FORM):
FLAGYL 200 (Tablets)
FLAGYL 400 (Tablets)
FLAGYL SUSPENSION (Suspension)

CONTENTS:
FLAGYL 200
Each tablet contains: Metronidazole 200 mg
Preservative: Methyl hydroxybenzoate 0.1 % m/m

Excipients:
Methyl hydroxybenzoate, maize starch, calcium carbonate, microcrystalline cellulose, potassium dihydrogen phosphate, sodium hydroxide, sodium lauryl sulphate, stearic acid and yellow dye (E 1914).

FLAGYL 400
Each tablet contains: Metronidazole 400 mg
Preservative: Methyl hydroxybenzoate 0.1 % m/m

Contains lartazaine.
Excipients: Methyl hydroxybenzoate, maize starch, calcium carbonate, microcrystalline cellulose, potassium dihydrogen phosphate, sodium hydroxide, sodium lauryl sulphate, stearic acid and yellow dye (E 1914).

FLAGYL SUSPENSION
Each 5 ml contains: Benzyl metronidazole equivalent to metronidazole 200 mg
Preservatives: Methyl hydroxybenzoate 0.08 % m/v
Propyl hydroxybenzoate 0.02 % m/v
Sucrose 3 g

Contains sugar.
Excipients: Sodium dihydrogen phosphate, methyl hydroxybenzoate, propyl hydroxybenzoate, ethanol, sucrose, vegetable h.v., lemon flavouring, oil of orange and water.

PHARMACOLOGICAL CLASSIFICATION:
A.20.2.6 Antimetabolite (chemotherapeutic) agents: Medicines against protozoa

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Metronidazole has antiprotozoal activity against *Trichomonas vaginalis* and other protozoa, including *Entamoeba histolytica* and *Giardia lamblia*. It does not affect the acidophilic flora of the vagina and it has no effect on *Candida* species. Metronidazole has bactericidal activity against obligate anaerobic bacteria, whether they are Gram positive or negative and bacilli or cocci.
It has well known activity against aerobic and facultative anaerobic bacteria. Metronidazole does not interfere with the activity of antibacterial agents which are active against a variety of aerobic and facultative anaerobes.
The following has been proposed as the mechanism of action of metronidazole: The parent compound penetrates the cell membrane unchanged, but once inside the cell the nitro group is reduced in the redox conditions prevalent in the anaerobic cell. The reduced product is known to damage DNA causing eventual death of the organism.
Pharmacokinetic properties:
Metronidazole is absorbed from the gastrointestinal tract and widely distributed in body tissues. Approximately 30-40 % of a dose is metabolised in the liver and excreted in the urine, together with the unchanged compound. Metronidazole is able to pass the blood-brain barrier. It reaches therapeutic concentrations in most other body fluids, i.e. saliva, bile, urine, amniotic fluid, breast milk and in abscess cavities.

INDICATIONS:
a) In the oral treatment of:
i) Genital trichomoniasis.
Non-specific vaginitis.
All forms of amoebiasis.
Bacterialis.
Acute ulcerative gingivitis (Vincent's).
ii) Acute peritonitis.
b) Treatment of infections in which anaerobic bacteria have been identified or are suspected as pathogens, particularly *Bacteroides fragilis* and other species of Bacteroides and including other species for which metronidazole is bactericidal, such as fusobacteria, clostridia, eubacteria and anaerobic streptococci.
c) Prevention of postoperative infections due to anaerobic bacteria:
i) Given before and after gynaecological surgery.
ii) Given before and after oesophagectomy.
iii) Given before and after colorectal surgery.
d) Treatment of *Helicobacter pylori*-associated gastritis and duodenal ulcer. FLAGYL is used in combination with bismuth subsalicylate or colloidal bismuth subcitrate and appropriate antibiotic therapy.

CONTRAINDICATIONS:
Hypersensitivity to metronidazole and other imidazoles.
Co-administration with busulfan (see WARNINGS and INTERACTIONS).

WARNINGS:
FLAGYL 400 tablets contain lartazaine which may cause allergic type reactions (including bronchial asthma) in certain individuals. Although the overall incidence of lartazaine cross-reactions in the general population is currently thought to be low, it is frequently seen in patients who also have aspirin sensitivity. Patients should be advised not to take alcohol during FLAGYL therapy and for at least one day afterwards because of the possibility of a disulfiram-like reaction (see INTERACTIONS).
Co-administration with busulfan: As plasma levels of busulfan are increased significantly, it may lead to severe busulfan toxicity and death.
Pseudo-membranous colitis has been reported with the use of FLAGYL.
Studies have shown FLAGYL may be mutagenic in bacteria and carcinogenic in some animals. FLAGYL should be administered with caution to patients with hepatic encephalopathy.

INTERACTIONS:
Disulfiram:
Acute psychosis or confusion have been associated with the concomitant use of FLAGYL and disulfiram.
Alcohol:
When given in conjunction with alcohol, FLAGYL may provoke a disulfiram-like reaction in some individuals (effects include intense vasodilation and flushing of the face and neck, rashes, urticaria, diarrhoea, tachypnoea, headache, nausea, vomiting, hyperreflexia, chest pains, sweating, jaundice and hypotension); reactions have occurred after the administration of pharmaceutical preparations formulated with alcohol, including injections, as well as after drinking alcohol.
Alcoholic beverages and medicinal containing alcohol should not be consumed during therapy and for at least 1 to 3 days afterwards (see WARNINGS).
Oral anti-coagulant therapy (warfarin type):
Potentiation of the anticoagulant effect and increased haemorrhagic risk. In case of co-administration with warfarin, prothrombin time(INR) should be more frequently monitored and warfarin therapy/dose adjusted during treatment with FLAGYL.
Lithium:
Plasma levels of lithium may be increased by FLAGYL. Plasma concentrations of lithium, creatinine and electrolytes should be monitored in patients under treatment with lithium while they receive FLAGYL.

Ciclosporin:
Risk of elevation of ciclosporin serum levels. Serum ciclosporin and serum creatinine should be closely monitored when co-administration is necessary.

Phenitoin or phenobarbital:
There is evidence that phenitoin might accelerate the metabolism of FLAGYL. Plasma concentrations of FLAGYL are decreased by the concomitant administration of phenobarbital with a consequent reduction in the effectiveness of FLAGYL.

5-Fluorouracil:
Cotreatment with 5-Fluorouracil resulting in increased toxicity of 5-Fluorouracil may occur.

Busulfan:
Plasma levels of busulfan may be increased by FLAGYL, which may lead to severe busulfan toxicity and death (see CONTRAINDICATIONS and WARNINGS).

Cimetidine:
Hepatic metabolism may be decreased when FLAGYL and cimetidine are used concurrently, possibly resulting in delayed elimination and increased serum metronidazole concentrations. There is also another risk of neurological side effects.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.
FLAGYL crosses the placental barrier and is excreted in breast milk. Use in pregnancy and lactation should be carefully evaluated.

DOSEAGE AND DIRECTIONS FOR USE:
The tablets should be taken with or after food.
FLAGYL SUSPENSION is administered orally. It is recommended that it be taken at least 1 hour before food.
Immature children and babies weighing less than 10 kg should receive proportionally smaller doses, as advised by the doctor. Children over 10 years may be given a suitable children's dose of the adult dosage according to body mass.

	DURATION OF DOSAGE IN DAYS	ADULTS	7 TO 10 YEARS	CHILDREN 3 TO 7 YEARS	1 TO 3 YEARS
UROGENITAL TRICHOMONIASIS: When used in combination with a suitable course of treatment concurrently.	1	2 g as a single dose			
	7	200 mg three times daily or 400 mg twice daily	100 mg three times daily	100 mg twice daily	50 mg three times daily
NON-SPECIFIC VAGINITIS	2	400 mg in the morning and 1.2 g in the evening			
	7	400 mg twice daily			
OR	1	2 g as a single dose			
AMOEBIASIS a) Invasive intestinal disease in susceptible infections.	5	800 mg three times daily	400 mg three times daily	200 mg four times daily	200 mg three times daily
	AMOEBIASIS b) Intestinal disease in less susceptible subjects and 'chronic amoebic hepatitis'.	5 to 10	400 mg three times daily	200 mg three times daily	100 mg four times daily
AMOEBIASIS c) Amoebic liver abscess, also other forms of extra-intestinal amoebiasis.		5	400 mg three times daily	200 mg three times daily	100 mg four times daily
AMOEBIASIS d) Symptomatic cyst passers.	5 to 10	400 to 800 mg three times daily	200 to 400 mg three times daily	100 to 200 mg four times daily	100 to 200 mg three times daily
	GIARDIASIS A second course of treatment may be necessary in some patients two weeks after the end of the first course.	3	2 g once daily	1 g once daily	600 to 800 mg once daily
ACUTE ULCERATIVE GINGIVITIS	3	200 mg three times daily	100 mg three times daily	100 mg twice daily	50 mg three times daily
ACUTE PERICORONITIS	3 to 7	200 mg three times daily			

Anaerobic infections
a) **Treatment:**
FLAGYL may be given alone or concurrently with other bacteriologically appropriate antibacterial agents. They should be given for 7 days or longer depending on clinical and bacteriological assessments of the patient's condition.
Adults: Initially, 800 mg followed by 400 mg by mouth every 8 hours.
Children: 7.5 mg/kg body mass by mouth every 8 hours.
b) **Prevention:**
Adults: Administered in doses similar to those used for the treatment of established infection. 400 mg may be given every 8 hours in the 24 hours before surgery followed postoperatively by intravenous or rectal administration until oral therapy is possible.
Children: As for treatment (a).
Treatment of Helicobacter pylori-associated gastritis and duodenal ulcer
The following regimens have been used:
a) Colloidal bismuth subcitrate 100 mg, tetracycline HCl 500 mg, FLAGYL 250 mg - 4 times a day for 14 days. To obtain a dosage of 250 mg FLAGYL (metronidazole), 6.25 ml of FLAGYL SUSPENSION should be administered.
b) Colloidal bismuth subcitrate 100 mg, tetracycline HCl 250 mg, FLAGYL 200 mg - 5 times a day for 14 days.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Side effects:
Metronidazole may cause a disulfiram-like reaction in some individuals (effects include intense vasodilation and flushing of the face and neck, rashes, urticaria, diarrhoea, tachypnoea, headache, nausea, vomiting, hyperreflexia, chest pains, sweating, jaundice and hypotension); reactions have occurred after the administration of pharmaceutical preparations formulated with alcohol, including injections, as well as after drinking alcohol.
Blood and the lymphatic system disorders:
Frequent unknown: Leucopenia may occur in some patients receiving FLAGYL.
Less frequent: Agranulocytosis, neutropenia and thrombocytopenia

Immune system disorders:
Less frequent: Angioedema.
Frequency unknown: Angioedema, urticaria

Metabolism and nutrition disorders:
Frequency unknown: Anorexia

Psychiatric disorders:
Less frequent: Psychotic disorders including confusion, irritability and hallucinations, changes in mood or mental state such as depression or confusion
Frequency unknown: Psychotic disorder, usually presenting as numbness or tingling in the extremities, and epileptiform seizures are serious adverse effects on the nervous system that have been associated especially with high doses of FLAGYL or prolonged treatment
Less frequent: Weakness, dizziness, drowsiness, insomnia. Reports of encephalopathy (e.g. confusion) and subacute cerebellar syndrome (e.g. ataxia, dysarthria, gait impairment, incontinence and tremor), which may resolve with discontinuation of the medicine.

Eye disorders:
Less frequent: The occurrence of transient vision disorders such as diplopia and miosis may follow the use of FLAGYL.

Respiratory, thoracic and mediastinal disorders:
Frequent unknown: Nasal congestion

Gastrointestinal disorders:
Frequent: Gastrointestinal disturbances, especially nausea and taste disorders; nausea is sometimes accompanied by headache, and vomiting. Diarrhoea, dry mouth, a furred tongue, oral mucositis and stomatitis.
Less frequent: Antibiotic-associated colitis.
Frequency unknown: Pseudo-membranous colitis

Hepato-biliary disorders:
Frequency unknown: Pancreatitis and raised liver enzyme values
Less frequent: Reversible abnormal liver function and cholestatic hepatitis sometimes with jaundice

Skin and subcutaneous tissue disorders:
Frequent unknown: Skin rashes, fever, flushing, and pruritus
Less frequent: Pustular eruptions, mild erythematous eruptions with fleeting joint pains resembling serum sickness

Musculoskeletal, connective tissue and bone disorders:
Frequency unknown: Myalgia and arthralgia

Renal and urinary disorders:
Less frequent: Urinary discolorant and darkening of the urine

Special Precautions:
FLAGYL should be used with great care in patients with blood dyscrasia or with active or chronic disease of the central and peripheral nervous system. All patients receiving FLAGYL for more than 10 days should be monitored and treatment discontinued if signs of peripheral neuropathy or central nervous system toxicity develop. Doses should be reduced in patients with severe liver disease.
FLAGYL has anti-reptilian activity and may mask the immunological response seen in untreated early syphils; contacts of syphils receiving FLAGYL should probably be screened for an additional 4 to 8 weeks.
Patients should be warned that FLAGYL may darken urine (due to metronidazole metabolites).
Studies have shown FLAGYL to be mutagenic in bacteria and carcinogenic in some animals.

DRIVING A VEHICLE OR PERFORMING HAZARDOUS TASKS:
Patients should be warned about the risks of confusion, dizziness, hallucinations, convulsions or transient visual disorders, and advised not to drive or operate machinery if these symptoms occur

Important information on sucrose and alcohol:
Sucrose:
FLAGYL SUSPENSION contains sucrose and may be harmful to patients who are sucrose intolerant.
Ethanol/Alcohol:
FLAGYL SUSPENSION contains 0.8 % alcohol (ethanol) by volume: this is equivalent to 32 mg alcohol per 5 ml dose. At high doses, this could be harmful for those suffering from alcoholism, hepatic disease or epilepsy.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See SIDE EFFECTS AND SPECIAL PRECAUTIONS above.
Treatment is symptomatic and supportive.

IDENTIFICATION:
FLAGYL 200 - Circular, off-white to cream biconvex tablets, impressed 'FLAGYL 200' on the one side.
FLAGYL 400 - Circular, yellow, biconvex tablets, impressed 'FLAGYL 400' on the one side, breakline on the reverse.
FLAGYL SUSPENSION - Off-white, coarse, suspension with an orange and lemon odour.

PRESSENTATION:
FLAGYL 200 - Containers of 21 and 250
FLAGYL 400 - Containers of 10 and 100
FLAGYL SUSPENSION - Bottles of 50 ml and 100 ml

STORAGE INSTRUCTIONS:
Store below 25 °C.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
FLAGYL 200 - A370 (Act 101/1965)
FLAGYL 400 - D/20.2.6/228
FLAGYL SUSPENSION - F/20.2.2/26

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
sanofi-aventis south africa (pty) ltd.
2 Bond Street,
Midrand
South Africa,
1685

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
2 March 2012

NAMIBIA Scheduling status: S2 Registration numbers: FLAGYL 400 - 90/20.2/003088 (Act No.13 of 2003) FLAGYL SUSPENSION - 90/20.2.6/003111 (Act No.13 of 2003)

PATIENT INFORMATION LEAFLET
Read this leaflet carefully before you start taking or giving FLAGYL.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, please ask your doctor or your pharmacist.
• FLAGYL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S2
PROPRIETARY NAME (AND DOSAGE FORM):
FLAGYL 200 (Tablets)
FLAGYL 400 (Tablets)
FLAGYL SUSPENSION (Suspension)
WHAT FLAGYL CONTAINS:
FLAGYL 200
Each tablet contains: Metronidazole 200 mg
Preservative: Methyl hydroxybenzoate 0.1 % m/m

Other ingredients are:
Maize starch, calcium carbonate, methyl hydroxybenzoate, sodium lauryl sulphate, stearic acid and microcrystalline cellulose.

FLAGYL 400
Each tablet contains: Metronidazole 400 mg
Preservative: Methyl hydroxybenzoate 0.1 % m/m

Contains lartazaine.
Other ingredients are:
Methyl hydroxybenzoate, maize starch, calcium carbonate, microcrystalline cellulose, potassium dihydrogen phosphate, sodium hydroxide, sodium lauryl sulphate, stearic acid and yellow dye (E 1914).

FLAGYL SUSPENSION
Each 5 ml contains: Benzyl metronidazole equivalent to metronidazole 200 mg
Preservatives: Methyl hydroxybenzoate 0.08 % m/v
Propyl hydroxybenzoate 0.02 % m/v
Sucrose 3 g

Contains sugar.
Other ingredients are:
Sodium dihydrogen phosphate, methyl hydroxybenzoate, propyl hydroxybenzoate, ethanol, sucrose, vegetable h.v., lemon flavouring, oil of orange and water.

WHAT FLAGYL IS USED FOR:
FLAGYL contains metronidazole, and it works by killing bacteria and parasites that cause infections in your body.
It can be used to:
- Treat infections caused by certain bacteria.
- Prevent infections after surgery.
If you need any further information on your illness, speak to your doctor.

BEFORE YOU TAKE FLAGYL:
Do not take FLAGYL and tell your doctor if:
- You are allergic (hypersensitive) to metronidazole or any of the other ingredients in FLAGYL. Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
Do not have FLAGYL if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before receiving FLAGYL. Do this even if they have applied in the past.
Take special care with FLAGYL and check with your doctor or pharmacist before having FLAGYL:
- If you have hepatic encephalopathy (worsening of brain function that occurs when the liver is no longer able to remove toxic substances in the blood).
- Alcohol beverages and medicinal containing alcohol should not be consumed during therapy and for at least 1 to 3 days afterwards. (see HAVING FLAGYL WITH FOOD AND DRINK).
- Pseudo-membranous colitis (infection of the colon) has been reported with the use of FLAGYL.
- Co-administration with busulfan (treatment for cancer of blood cells) may lead to severe busulfan toxicity and death. Do this even if they have applied in the past.
If you are not sure of any of the above-appears to you, talk to your doctor or pharmacist before receiving FLAGYL. Do this even if they have applied in the past.

Having FLAGYL with food and drink:
Do not drink any alcohol while you are having FLAGYL, and for 1 to 3 days after finishing your course. Drinking alcohol whilst you are being treated with FLAGYL might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flashes, very fast or uneven heartbeat (palpitations) and headache.

Pregnancy and breastfeeding:
Tell your doctor before using FLAGYL if:
- You are pregnant, might become pregnant or think you may be pregnant. FLAGYL should not be taken during pregnancy unless considered absolutely necessary, and
- You are breastfeeding. This is because small amounts of FLAGYL may pass into the mother's milk.
If you are pregnant or breastfeeding your baby while taking FLAGYL, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:
While taking FLAGYL, you may feel sleepy, dizzy, confused, or see or hear things that are not there (hallucinations), or have fits (convulsions) or temporary eye-vision problems (such as feeling double vision). If this happens, do not drive or use any machinery or tools.

Important information about some of the ingredients of FLAGYL:
Sucrose:
FLAGYL contains sucrose and may be harmful to patients who are sucrose intolerant.
Methyl hydroxybenzoate and propyl hydroxybenzoate:
These are preservatives that are added to FLAGYL to make the medicine last longer. These can cause an allergic reaction in some people.
Alcohol:
FLAGYL contains 0.8 % alcohol (ethanol) by volume: this is equivalent to 32 mg alcohol per 5 ml dose. At high doses, this could be harmful for those suffering from alcoholism, liver disease or epilepsy.

Taking other medicines with FLAGYL:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because FLAGYL can affect the way some other medicines work. Also, some other medicines can affect the way FLAGYL works.
In particular, tell your doctor if you are taking any of the following medicines:
- Disulfiram for the treatment of alcoholism
- Alcohol or medicine containing alcohol.
- Medicines used to thin the blood such as warfarin.
- Lithium for mental illness.
- Phenytoin or phenobarbital for epilepsy.
- 5-Fluorouracil for cancer.
- Busulfan for leukaemia (cancer of the blood cells).
- Ciclosporin to prevent the rejection of organs after transplant.
- Cimetidine for stomach ulcers.
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of FLAGYL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional.

Tests:
Your doctor may wish to carry out some tests if you have been using FLAGYL for more than 10 days.

HOW TO TAKE FLAGYL:
Taking your medicine:
Always take FLAGYL exactly as your doctor has instructed you. It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated. You should check with your doctor or pharmacist if you are not sure.

TABLETS
- Swallow the tablets whole with a little water.
- Do not crush or chew the tablets.
- Take these tablets during or just after a meal.
- The dose of FLAGYL will depend on your needs and the illness being treated.
- The length of your treatment will depend on the type of illness you have and how bad it is.

SUSPENSION
- Shake well before use.
- Take FLAGYL SUSPENSION by mouth.
- Take the suspension at least 1 hour before food.
- The dose of FLAGYL will depend on your needs and the illness being treated.
- The length of your treatment will depend on the type of illness you have and how bad it is.

The usual dose for adults and children is given below:
To treat bacterial infection:
Adults:
- The initial dose is 800 mg.
- After 8 hours, take another dose of 400 mg and repeat this dose every 8 hours. The dosage may vary depending on the condition being treated.
Children:
- Your doctor will work out how much your child should take, depending on their weight.
- Repeat the dose every 8 hours.
To prevent infections from happening after surgery:
Adults:
- Start taking FLAGYL tablets 24 hours before your operation.
- Take 400 mg of FLAGYL every 8 hours.
- After the operation, you may be given FLAGYL either through a drip into a vein or rectally as a suppository until you are able to take tablets again.
Children:
- Start giving your child FLAGYL tablets 24 hours before their operation.
- Your doctor will work out how much your child should take, depending on their weight.
- Repeat the dose every 8 hours.
- After the operation, your child may be given FLAGYL either through a drip into a vein or rectally as a suppository until they are able to take tablets again.

If you take more FLAGYL than you should:
If you take more FLAGYL than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the carton and bottle with you. This is so the doctor knows what you have taken.

If you forget to take FLAGYL:
If you forget to take FLAGYL, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

POSSIBLE SIDE EFFECTS:
FLAGYL can have side effects.
Not all side effects reported for FLAGYL are included in this leaflet. Should your general health worsen while taking FLAGYL, please consult your doctor, pharmacist or other healthcare professional for advice.
Stop taking FLAGYL and see a doctor, or go to a hospital straight away if:
- You get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean that you are having an allergic reaction to FLAGYL.
- A serious but rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache and see or hear things that are not there. You might also have problems using your arms and legs, problems with speaking or feel confused.

Talk to your doctor straight away if you notice the following side effects:
- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexplained infections, mouth ulcers, bruising, bleeding gums or severe tiredness. This could be caused by a blood problem.
- Severe stomach pain which may also be felt in your back (pancreatitis).

Tell your doctor or pharmacist if you notice any of the following side effects:
Less frequent:
- Fish (vomiting)
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- Problems with your eyesight such as blurred or double vision
- Skin rash
- Headache
- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Numbness, tingling, pain or a feeling of weakness in the arms or legs
- Unpleasant taste in the mouth
- Furred tongue
- Feeling sick (nausea), being sick (vomiting), upset stomach or diarrhoea
- Loss of appetite

STORING AND DISPOSING OF FLAGYL:
KEEP YOUR MEDICINE IN A SAFE PLACE AND OUT OF THE REACH AND SIGHT OF CHILDREN.
Store below 25 °C.
Store your medicine in the original packaging in order to protect from light.
Do not use this medicine after the expiry date shown on the packaging.
Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF FLAGYL:
FLAGYL 200 - Containers of 21 and 250
FLAGYL 400 - Containers of 10 and 100
FLAGYL SUSPENSION - Bottles of 50 ml and 100 ml

IDENTIFICATION OF FLAGYL:
FLAGYL 200 - Circular, off-white to cream biconvex tablets, impressed 'FLAGYL 200' on the one side.
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FLAGYL SUSPENSION - Off-white, coarse, suspension with an orange and lemon odour.

REGISTRATION NUMBERS:
FLAGYL 200 - A370 (Act 101/1965)
FLAGYL 400 - D/20.2.6/228
FLAGYL SUSPENSION - F/20.2.2/26

NAME AND ADDRESS OF REGISTRATION HOLDER:
sanofi-aventis south africa (pty) ltd.
2 Bond Street,
Midrand
South Africa,
1685

DATE OF PUBLICATION:
2 March 2012

SAP/JID number:	EG08235
Country:	South Africa
Registered name:	Flagyl [®]
Version number:	Version 7
Date:	23/08/12
Dimensions:	930 x 160 mm
Copy:	DRA
Item:	PI/PIRL
Logo version:	N/A
Operator:	Pete
SANA bar code:	N/A
Pharmacode:	101
Item code:	484246
Screen:	150#
Material:	Press PDF on CD
Deadline for material:	TBA
Min. point size of text:	5.4 pt
COLOURS:	Pantone Reflex Blue CVC ●
Approval of text:	Date:
	Signature:
Final approval:	Date:
	Signature:

