PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

FLAGYL SUSPENSION : each 5 mL of suspension contains benzoyl metronidazole equivalent to metronidazole 200 mg

Contains sugar: sucrose 3 g/5 mL

Preservatives: methyl hydroxybenzoate 0,08 % *m/v* and propyl hydroxybenzoate 0,02 % *m/v*

For excipients, see section 6.1.

Read all of this leaflet carefully before you or your child start taking FLAGYL:

- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor or [~~your~~] pharmacist, nurse or other health care provider
- FLAGYL has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1 What FLAGYL is and what it is used for

2 What you need to know before you take or give FLAGYL to your child

3 How to receive FLAGYL

4 Possible side effects

5 How to store FLAGYL

6 Contents of the pack and other information.

1. WHAT FLAGYL IS AND WHAT IT 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 or your child need any further information on your illness, speak to your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OR GIVE FLAGYL TO YOUR CHILD:

Do not take FLAGYL or give FLAGYL to your child if:

- You or your child are allergic (hypersensitive) to metronidazole or any of the other ingredients in FLAGYL. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You or your child are taking the medicine, busulfan (treatment for cancer of blood cells). (See Warnings and precautions and OTHER MEDICINES AND FLAGYL).

If you are not sure, talk to your doctor or pharmacist before taking or giving FLAGYL to your child.

Warnings and precautions:

You should tell your doctor or pharmacist before taking or giving FLAGYL to your child:

- **If you or your child have blood dyscrasias (disease of the blood with low/lack of certain blood cells) or active or chronic disease of the central (nerves of the brain and spinal cord) and peripheral (nerves outside the brain and spinal cord) nervous system**
- If you or your child have hepatic encephalopathy (worsening of brain function that occurs when the liver is no longer able to remove toxic substances in the blood).

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with FLAGYL. If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with FLAGYL and afterwards. Tell your doctor immediately and stop taking FLAGYL if you develop: stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching (see section 4)

- If you or your child receives treatment for cancer of blood cells. Co-administration with busulfan may lead to severe busulfan toxicity and death.

Serious skin reactions including Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of FLAGYL

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life threatening complications or be fatal
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk and upper extremities.

The highest risk for occurrence of serious skin reactions is within one week, typically, within 48 hours of treatment. If you develop a serious rash or another of these skin symptoms, stop taking FLAGYL and contact your doctor or seek medical attention immediately (see section 4).

Some people being treated with metronidazole can experience mental health problems such as irrational thoughts, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide. These symptoms can occur even in people who have never had similar

problems before. If you or others around you notice any of these side effects stop taking this medicine and seek medical advice straight away.

Do not take alcohol beverages and medicine containing alcohol during therapy and for at least 1 to 3 days afterwards (see TAKING FLAGYL WITH FOOD AND DRINK and ALCOHOL).

Pseudomembranous colitis (infection of the colon) has been reported with the use of FLAGYL. Tell you or your child's doctor immediately if you develop watery and severe diarrhoea, which may also be bloody.

If you or your child are taking FLAGYL for more than 10 days your doctor will monitor you and will discontinue treatment if signs of peripheral neuropathy (disorder of the nerves which can cause weakness, tingling or numbness) or central nervous system toxicity develop. Your doctor will lower the dose of FLAGYL if you suffer with severe liver disease.

FLAGYL has anti-treponemal activity (bacteria that can cause syphilis) and may mask the immunological response (the body's natural defence) seen in untreated early syphilis. If you have syphilis and are receiving FLAGYL your doctor will continue testing you for syphilis for an additional 4 to 8 weeks.

FLAGYL may cause darkening of urine (due to the substance that FLAGYL is broken down into in the body).

If you are not sure if any of the above applies to you or your child, talk to your doctor or pharmacist before taking FLAGYL.

Other medicines and FLAGYL:

Always tell your healthcare professional if you or your child are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor if you or your child are taking any of the following medicines:

- Disulfiram for the treatment of alcoholism. Taking FLAGYL with disulfiram can result in acute confusion.
- Medicines used to thin the blood such as warfarin. FLAGYL intensifies the effect of warfarin and may result in uncontrolled bleeding
- Lithium for mental illness. Blood levels of lithium may be increased by FLAGYL
- Phenytoin or phenobarbital for epilepsy reduce the effectiveness of FLAGYL
- 5-Fluorouracil for cancer. FLAGYL may intensify the of harmfull effects of 5-fluorouracil
- Busulfan for leukaemia (cancer of the blood cells) (see Take special care with FLAGYL)
- Ciclosporin to prevent the rejection of organs after transplant. FLAGYL may increase the blood levels of ciclosporin
- Cimetidine for stomach ulcers may intensify the effects of FLAGYL.

FLAGYL with food and drink and alcohol:

Do not drink any alcohol or medicine containing alcohol while you or your child are taking 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 flushes, very fast or uneven heartbeat (palpitations) and headache.

Pregnancy and breastfeeding and fertility:

Safety in pregnancy and lactation has not been established.

Tell your doctor before taking FLAGYL if:

- You are pregnant, might become pregnant or think you may be pregnant.
- You are breastfeeding. FLAGYL pass into the mother's milk and women taking FLAGYL should not breastfeed their infants.

If you are pregnant or breastfeeding your baby while taking FLAGYL, please consult your doctor, pharmacist or other healthcare professional for advice before taking FLAGYL.

Driving and using machinery:

While taking FLAGYL, you or your child may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision. (See POSSIBLE SIDE EFFECTS). If this happens, do not drive or use any machinery or tools.

FLAGYL suspension contains:

- Sucrose is a type of sugar which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you or your child have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FLAGYL SUSPENSION
- Methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) are preservatives that are added to FLAGYL to make the medicine last longer. These can cause an allergic reaction in some people
- FLAGYL suspension contains 0,8 % alcohol (ethanol) by volume; this is equivalent to 32,5 mg alcohol per 5 ml dose. This small amount of alcohol will not have any noticeable effects.

3. HOW TO TAKE FLAGYL:

Do not share medicines prescribed for you with any other person.

Taking your medicine:

Always take FLAGYL exactly as your doctor has instructed you or your child. 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.

If you have the impression that the effect of FLAGYL is too strong or too weak, tell your doctor or pharmacist.

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.

If you or your child take or receive more FLAGYL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you or your child forget to take FLAGYL:

If you or your child 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.

4. POSSIBLE SIDE EFFECTS:

FLAGYL can have side effects.

Not all side effects reported for FLAGYL are included in this leaflet. Should you or your child's general health worsen or if you experience any untoward effects while taking FLAGYL, please consult your doctor, pharmacist or other healthcare professional for advice.

Blood and the lymphatic system disorders:

Less frequent: agranulocytosis, neutropenia and thrombocytopenia (blood problems with unexpected infections, mouth ulcers, bleeding or bruising more easily than normal)

Frequency unknown: leucopenia (lack of white blood cells)

Immune system disorders:

Less frequent: anaphylaxis (sudden life-threatening allergic reaction). See Warnings and precautions.

Frequency unknown: angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing), urticaria (pinkish, itchy, lumpy rash called hives or nettle rash)

Metabolism and nutrition disorders:

Frequency unknown: anorexia loss of appetite)

Psychiatric (mental) disorders:

Less frequent: psychotic disorders including confusion, irritability and hallucinations (seeing or hearing things that are not there), changes in mood or mental state such as depression or confusion

Nervous system disorders:

Less frequent: weakness, dizziness, drowsiness, insomnia (sleep disorder). Reports of encephalopathy (brain disease, symptoms of which vary but you may get a fever, stiff neck, headache and see or hear things that are not there) and subacute cerebellar syndrome (where you encounter problems with coordination of movement of your arms and legs, problems speaking or feel confused.

Frequency unknown: peripheral neuropathy (a disorder of the nerves), usually presenting as numbness, tingling, or a feeling of weakness in the arms or legs and, fits (convulsions) are serious adverse effects on the nervous system that have been associated especially with high doses of FLAGYL of prolonged treatment

Eye disorders:

Less frequent: vision disorders such as diplopia (double vision) and myopia (short sightedness)

Respiratory, thoracic and mediastinal (breathing and chest) disorders:

Frequency unknown: nasal congestion (blocked/stuffy nose)

Gastrointestinal (stomach and intestines) disorders:

Frequent: gastrointestinal disturbances, especially nausea (feeling sick) and taste disorders; nausea is sometimes accompanied by headache, and vomiting (being sick). Diarrhoea, dry mouth, a furred tongue, oral mucositis (sore/red mouth) and stomatitis (sore mouth, mouth ulcers and cold sores)

Less frequent: pseudomembranous colitis (watery and severe diarrhoea, which may also be bloody)

Hepato-biliary (liver-bile duct) disorders:

Less frequent: increase in liver enzymes (liver problem) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine

Frequency unknown: pancreatitis (inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting) and raised liver enzyme values (liver problem)

Skin and subcutaneous tissue (under the skin) disorders:

Less frequent: pustular eruptions (breakouts of blisters, containing pus, on the skin), mild erythematous eruptions (mild redness) with fleeting (brief) joint pains resembling serum sickness (allergic reaction to an injection of serum)

Frequency unknown: skin rashes, fever, flushing (reddening of skin), and pruritus (itching)

Musculoskeletal (muscle and skeleton), connective tissue (body packing tissue) and bone disorders:

Frequency unknown: myalgia (pains in the muscles) and arthralgia (pains in the joints)

Renal (kidney) and urinary (bladder) disorders:

Less frequent: urethral (bladder) discomfort and darkening of the urine

General disorders and administration site conditions:

Frequency unknown: fever

The frequency of the following side effects is unknown:

Nervous system disorders:

headache, aseptic meningitis (inflammation of the membranes around the brain and spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light (see Warnings and precautions), sensations of spinning

Eye disorders:

eyesight problems such as blurred vision, decreased in visual acuity (sharpness of vision), changes in colour vision, optic neuritis (pain in your eyes and increasingly blurred vision)

Ear and labyrinth disorders:

hearing impaired/hearing loss (including nerve deafness), tinnitus (ringing in your ears)

Gastrointestinal (stomach and intestines) disorders:

epigastric pain (pain in the upper central region of the stomach)

Hepato-biliary (liver and bile-duct) disorders:

mixed hepatitis and hepatocellular liver injury (liver diseases), cases of liver failure requiring liver transplant have been reported in patients treated with FLAGYL in combination with other antibiotic medication

Skin and subcutaneous tissue disorders:

acute generalized exanthematous pustulosis (red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment), fixed drug eruption.

Stevens Johnson syndrome, toxic epidermal necrolysis. Skin rash can appear as reddish target-like spots or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using FLAGYL if you develop these symptoms and contact your doctor or seek medical attention immediately (see Warnings and precautions).

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly to Sanofi's Pharmacovigilance Unit at Email: za.drugsafety@sanofi.com or Tel: 011 256 3700 or

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of FLAGYL.

5 HOW TO STORE FLAGYL:

Store all medicines out of reach of children.

Store at or 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).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What FLAGYL contains:

The active substance is metronidazole (as benzoyl metronidazole).

The other ingredients are:

Ethanol, lemon flavouring, methyl hydroxybenzoate (E218), oil of orange, propyl hydroxybenzoate (E216), sodium dihydrogen phosphate, sucrose, veegum H.V. and water.

FLAGYL SUSPENSION: Off-white, coarse, oral suspension with an orange and lemon odour; packed in amber glass bottles in pack sizes of 50 ml and 100 ml suspension.

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd.

2 Bond Street,

Midrand

South Africa,

1685

This leaflet was last revised in:

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REGISTRATION NUMBERS:

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