APPROVED PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS

S4

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM

ANAEROBYL 200 (TABLETS)

ANAEROBYL 400 (TABLETS)

Read all of this leaflet carefully before you start taking ANAEROBYL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ANAEROBYL** 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.

WHAT ANAEROBYL CONTAINS

The active substance:

Each **ANAEROBYL 200** tablets contain metronidazole 200 mg.

Each **ANAEROBYL 400** tablets contain metronidazole 400 mg.

Other ingredients are: Microcrystalline cellulose (avicel pH 200), stearic acid.

Sugar free.

WHAT ANAEROBYL IS USED FOR

ANAEROBYL works by killing bacteria and parasites that cause infections in your body.

It can be used:

- to treat infections caused by certain bacteria (genital infections, stomach and intestine infections and dental infections)

- Prevention of infections after surgery

If you need any further information on your illness, speak to your doctor.

BEFORE YOU TAKE ANAEROBYL

Do not take ANAEROBYL:

- If you are or have a prior history of hypersensitivity (allergic) to metronidazole or other nitroimidazole derivatives, or any of the other ingredients of **ANAEROBYL.**

  Signs of an allergic reaction may include:

  o skin rash

  o swelling of the face, lips, throat or tongue which may cause difficulty in swallowing or breathing
- If you are pregnant or breastfeeding
- If you have a history or evidence of blood disorders

Take special care with ANAEROBYL:

- In patients with central nervous system diseases.
- convulsive seizures and peripheral neuropathy (numbness or paraesthesia of an extremity), have been reported
- alcoholic beverages should not be consumed during **ANAEROBYL** therapy because of the unpleasant side-effects.
- the appearance of abnormal neurologic signs requires immediate assessment
- in patients with hepatic disease, result slow metabolism in increased plasma levels of metronidazole and its metabolites.

Special precautions:

- Incision and draining of an abscess should be performed in conjunction with **ANAEROBYL** treatment.

- In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to **ANAEROBYL. ANAEROBYL** is not effective against aerobic or facultative anaerobic organisms.

Having ANAEROBYL with food and drink:

Do not drink any alcohol while you are having **ANAEROBYL** and for 1 to 3 days after finishing your course. Drinking alcohol whilst you are being treated with **ANAEROBYL** 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 (see **"Take special care with ANAEROBYL").**
The tablets should be taken at or after meals.

Pregnancy and Breastfeeding:

ANAEROBYL is contraindicated for use during pregnancy and breastfeeding (see " **BEFORE YOU TAKE ANAEROBYL")**

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

Driving and using machinery:

While taking **ANAEROBYL,** you may feel sleepy, dizzy, confused or you may faint. If this happens, do not drive or use any machinery or tools.

Taking other medicines with ANAEROBYL

- **ANAEROBYL** has been reported to potentiate the activity of warfarin and other oral coumarin anticoagulants (blood thinning medicine). There is no interaction with heparin.
- Patients receiving concurrent therapy with medicine inducing microsomal enzymes, such as phenytoin and phenobarbitone (to treat epilepsy), may reduce plasma levels.

Laboratory tests:

- **ANAEROBYL** may interfere with certain chemical analyses for aspartate aminotransferase (AST, SGOT), alanine aminotransferase (ALT**,** SGPT) triglycerides and glucose using the hexokinase method resulting in decreased values.

HOW TO TAKE ANAEROBYL

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

Adults and Children:

Always take **ANAEROBYL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dose and length of time you have to take **ANAEROBYL** will depend on the type of infection you have and your doctor will tell you how long your treatment with **ANAEROBYL** will last.

Do not stop treatment early even though the symptoms have been alleviated.

If your symptoms do not improve within a few days or become worse, please contact your doctor.

If you get the impression that the effect of **ANAEROBYL** is too strong or too weak, talk to your doctor or pharmacist.

Do not exceed 4,0 grams in 24 hours.

The tablets should be taken at or after meals.

To prevent infections from happening after surgery:

The usual dose for adults:

- Start taking **ANAEROBYL** tablets 24 hours before your operation

- Take 400 mg **ANAEROBYL** every 8 hours

- After the operation, you may be given **ANAEROBYL** either through a drip into a vein or rectally as a suppository until you are able to take tablets again

If you take more ANAEROBYL than you should:

If you take more **ANAEROBYL** than you should and you start to experience feeling sick (nausea), being sick (vomiting) and uncoordinated movement (ataxia), neurotoxic effects, including seizures and numbness or paraesthesia of an extremity (peripheral neuropathy), consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ANAEROBYL:

Take the missed dose as soon as you remember it. However, if it is almost time for your next regular dose, do not take your missed dose. If you miss two or more doses, consult your doctor or pharmacist.

Do not take a double dose to make up for forgotten individual doses.

Possible side effects

ANAEROBYL can have side effects.

If any of the following happens, stop taking ANAEROBYL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- severe skin rash, blistering or peeling of the skin or itching
- fainting

These are all serious side effects. If you have them you may have had a serious allergic reaction to **ANAEROBYL.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- gastrointestinal symptoms such as feeling sick (nausea), being sick (vomiting), abdominal discomfort and unpleasant metallic taste
- reversible abnormally low count of neutrophils (neutropenia)
- redness (erythematous) rash and itching (pruritus)

- headache, dizziness, and fainting (syncope)
- fever
- darkened urine, which appears to have no clinical significance
- painful urination (dysuria), inflammation of the bladder (cystitis) or excessive passage of urine (polyuria)
- flattening of the T-wave in electrocardiographic (electrical activity of the heart) tracings
- candida overgrowth may occur during therapy with **ANAEROBYL** and should be treated with a candicidal agent
- a mild decrease in white cell count (leucopenia) has been observed; however, no persistent blood abnormalities have been observed.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ANAEROBYL

Store all medicine out of reach of children.

Store at or below 25 ºC. Protect from moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ANAEROBYL

ANAEROBYL 200 tablets:

Rectangular or round amber glass bottles containing 21 or 500 tablets.

Securitainers containing 21 or 500 tablets, and HDPE containers containing

1 000 tablets.

White Low Density Polyethylene plastic Patient Ready Packs containing different pack sizes.

ANAEROBYL 400 tablets:

Rectangular or round amber glass bottles containing 10 or 500 tablets.

Securitainers containing 10 or 500 tablets, and HDPE containers containing

1 000 tablets.

White Low Density Polyethylene plastic Patient Ready Packs containing different pack sizes.

IDENTIFICATION OF ANAEROBYL

ANAEROBYL 200 tablets:

White to off-white round biconvex tablets 9,5 mm in diameter with breakline on one face.

ANAEROBYL 400 tablets:

White to off-white, round shape tablets with breakline on one side.

REGISTRATION NUMBERS

ANAEROBYL 200 tablets: R/20.2.6/300

ANAEROBYL 400 tablets: R/20.2.6/301

NAME AND BUSINESS HOLDER REGISTRATION:

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