SCHEDULING STATUS

S4

METRAZOLE, 400 mg, tablets

Metronidazole

Contains sugar as 80 mg lactose per tablet

Read all of this leaflet carefully before you start taking METRAZOLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- METRAZOLE 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 is in this leaflet

1 What METRAZOLE is and what it is used for

2. What you need to know before you take METRAZOLE

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1. What METRAZOLE is and what it is used for

METRAZOLE contains metronidazole. This belongs to a group of medicines called antibiotics. It works by killing bacteria and parasites that cause infections in your body.

It can be used to:

- Treat infections in your body.
- Prevent infections after surgery.

2. What you need to know before you take METRAZOLE

Do not take METRAZOLE

- If you are hypersensitive (allergic) to metronidazole, other imidazoles (a class of medicines used to treat fungal infections), or any of the other ingredients of METRAZOLE (listed in section 6).
- If you have been diagnosed with blood dyscrasias or with active disease of your nervous system.
- If you are pregnant.
- When taking busulfan (treatment for cancer of blood cells) (see sections Special care should be taken with METRAZOLE and Other medicines and METRAZOLE).

Warnings and precautions

Special care should be taken with METRAZOLE

- If you take alcohol. You might have a severe reaction leading to nausea, vomiting, flushing, dizziness, throbbing headache, chest and abdominal discomfort, and general hangover-like symptoms among others (see METRAZOLE with alcohol)
- If you are taking warfarin or other blood thinning medications. Your doctor might need to change the dosage of these medicines.
- If you are taking busulfan (treatment for cancer of blood cells). You should not take busulfan together with METRAZOLE (see Do not take METRAZOLE). METRAZOLE can

increase the toxic effects of busulfan. Your doctor might change the treatment (see Other medicines and METRAZOLE).

- If you develop watery and severe diarrhoea, which may also be bloody, you might develop a condition called Pseudomembranous colitis (infection of the colon). Tell your doctor immediately to receive the correct treatment.
- If you are on high blood pressure medication. Your doctor might need to lower the dosage of these medicines.
- If you are taking METRAZOLE for long periods (more than 10 days) at high dosages your doctor will monitor you and will discontinue treatment if signs of bone marrow depression (a laboratory test will show that blood cells decreased, causing you to feel tied, have a pale skin, lips and nails, shortness of breath and feeling dizzy) or (peripheral neuropathy (disorder of the nerves which can cause weakness, tingling or numbness).
- If you have syphilis, blood tests to confirm that you are infected can be hidden when using METRAZOLE. Your doctor might test you for syphilis for an additional 4 to 8 weeks after using METRAZOLE.
- Note that your urine can become dark while using METRAZOLE. You need not worry if this happens as the colour is due to your body removing METRAZOLE from your system.
- If you have liver disease, your doctor might lower the METRAZOLE dosage.
- If you have Cockayne syndrome your doctor should monitor your liver function frequently while you are being treated with METRAZOLE. Tell your doctor immediately and stop taking METRAZOLE if you develop the following symptoms: Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, putty or mastic-coloured stools or itching.
- If you develop serious skin rashes, often after developing fever and/or flu-like symptoms stop taking METRAZOLE and go to your doctor or nearest hospital immediately. The skin reaction appears initially as reddish target-like spots or circular patches often with

blisters on your body and also as sores in your mouth, throat, nose, genitals and eyes (red and swollen eyes. The rashes may become widespread peeling of the skin and can be life-threatening. These serious skin reactions include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP) (see section 4).

- If you have severe liver disease, your doctor might lower the METRAZOLE dosage.
- If you have liver failure, treatment with METRAZOLE should be stopped.
- If you have renal failure and are undergoing haemodialysis, you should take another dose of METRAZOLE after the haemodialysis. This is not necessary if you are undergoing peritoneal dialysis.

Other medicines and METRAZOLE

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

- Alcohol. You should not take METRAZOLE together with alcohol or within 3 days after taking alcohol. You can have a severe reaction leading to nausea, vomiting, flushing, dizziness, throbbing headache, chest and abdominal discomfort, and general hangover-like symptoms among others.
- Warfarin or other medicines used to thin your blood. METRAZOLE intensifies the effect of these medicines and can result in uncontrolled bleeding.
- Cimetidine used for stomach ulcers can increase the effects of METRAZOLE.
- Disulfiram for the treatment of alcoholism. Taking METRAZOLE with disulfiram or within 2 weeks after taking disulfiram can result in acute confusion and other reactions.
- Lithium used for mental illness. Blood levels of lithium can be increased by METRAZOLE.
- Phenobarbital and phenytoin used for epilepsy reduces the effect of METRAZOLE.

- Busulfan for the treatment of cancer of blood cells. METRAZOLE can increase the blood levels of busulfan to dangerously high levels (see Do not take METRAZOLE and Special care should be taken with METRAZOLE).
- Ciclosporin used to prevent the rejection of organs after transplant. METRAZOLE can increase the blood levels of ciclosporin.
- 5-Fluorouracil used for cancer treatment. METRAZOLE can intensify the of harmful effects of 5-fluorouracil.
- Medicine that may cause heart rhythm disturbances (so called QT prolongation which can be seen on ECG) such as certain anti-arrhythmic (medicines for heart rhythm disorders), certain antibiotics and medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought).

METRAZOLE with alcohol

Do not drink any alcohol or medicine containing alcohol while you are taking METRAZOLE and for 3 days after finishing your course.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking METRAZOLE. METRAZOLE should not be taken when you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent METRAZOLE may interfere with your daily activities. METRAZOLE can make you 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 section 4). You should ensure that you do not engage in

activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which METRAZOLE affects you.

METRAZOLE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking METRAZOLE.

3. How to take METRAZOLE

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

Always take METRAZOLE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For adults the dose of METRAZOLE will depend on your needs and the infection being treated.

For children older than 10 years, who can swallow tablets, your doctor will calculate the dosage depending on the child's weight.

Swallowed (without chewing) the tablets with a half glass of water. It is recommended to take the tablets during or after a meal.

Your doctor will tell you how long your treatment with METRAZOLE will last. Do not stop treatment early because the infection might return. If you have the impression that the effect of METRAZOLE is too strong or too weak, tell your doctor or pharmacist.

If you take more METRAZOLE than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take METRAZOLE

If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

METRAZOLE can have side effects.

Not all side effects reported for METRAZOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METRAZOLE, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing You can have an allergic reaction to METRAZOLE.
- A serious side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.
- Watery and severe diarrhoea, which may also be bloody, you might develop a condition called Pseudomembranous colitis (infection of the colon) (see also section 2).
- Severe blistering of your skin. These serious skin reactions include Steven-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP) (see also section 2).

- Increase in liver enzymes (blood tests) 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)
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (Pancreatitis).

These are all very serious side effects. If you have them, you may have had a serious reaction to METRAZOLE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following

Frequent side effects

- Dry mouth
- Unpleasant metallic taste
- Diarrhoea
- Nausea or vomiting
- Stomach pain or cramps
- Hairy tong

Less frequent side effects

- Blood tests show low blood cell count. You can have unexpected infections, mouth ulcers, bleeding or bruising more easily than normal
- Swelling of e.g. lips, eyes (angioedema)
- Loss of appetite
- 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

- Loss of balance and coordination (ataxia)
- Headache
- Dizziness or light headedness
- Seizures
- Difficulty to sleep
- Weakness, tingling or numbness, usually of hand and feet (peripheral neuropathy)
- Fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light (meningitis)
- Vision disorders such as diplopia (double vision), myopia (short sightedness), blurry vision or changes in vision colours
- Pain in your eyes (optic neuritis)
- Hearing impairment/ hearing loss
- Ringing in the ears (tinnitus)
- Blocked nose (nasal congestion)
- Skin rashes
- Pustular eruptions (breakouts of blisters, containing pus, on the skin)
- Pruritus (itching)
- Flushing (reddening of skin)
- Myalgia (pains in the muscles)
- Arthralgia (pains in the joints)
- Dark urine
- Painful of difficulty to urinate, bladder discomfort
- Fever

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

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 also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

In addition, side-effects can also be reported to info@pharmacorp.co.za.

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

5. How to store METRAZOLE

Store all medicines out of reach of children.

- Store in a cool place at or below 25 °C out of direct sunlight.
- 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 METRAZOLE contains

The active substance is metronidazole.

Each tablet contains 400 mg metronidazole.

The other ingredients are lactose; magnesium stearate; quinoline yellow (C.I. 47005), starch, maize; starch, pregelatinised; talc.

What METRAZOLE looks like and contents of the pack

Yellow, round, flat tablet, scored on one side.

The tablets are placed in either of the following containers:

5 tablets are packed in aluminium/clear PVC blisters.

10, 100, 500, 1000 or 5000 tablets are packed in either white/turquoise HDPE bottles, white polypropylene securitainers or white/amber PVC bottles, containing either absorbent cotton wool or foam wadding and closed with either white polypropylene, LDPE or HDPE caps.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pharmacorp (Pty) Ltd

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

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Access to the corresponding Professional Information

(and the translated Patient Information Leaflet)

www.pharmacorp.co.za