Patient Information Leaflet

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

BEMETRAZOLE 200 mg tablet

Metronidazole

Contains Sugar: Lactose 100 mg per tablet

BEMETRAZOLE 400 mg tablet

Metronidazole

Contains Sugar: Lactose 80 mg per tablet

Read all of this leaflet carefully before you start taking BEMETRAZOLE

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

BEMETRAZOLE 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.

2. What you need to know before you take BEMETRAZOLE

Do not take BEMETRAZOLE :

- If you are hypersensitive (allergic) to metronidazole or any of the other ingredients of BEMETRAZOLE (listed in section 6)

  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- If you have a disease or disorder ,especially of the blood

- If you are taking the medicine, busulfan (treatment for cancer of blood cells).

Do not take BEMETRAZOLE if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before receiving BEMETRAZOLE. Do this even if they have applied in the past

Warnings and precautions

Take special care with BEMETRAZOLE :

- 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).
- If you have severe liver toxicity/acute liver failure with Cockayne syndrome (neuro degenerative disorder characterised by growth failure, no development of the nervous system, abnormal sensitivity to sunlight, eye disorders and premature aging)have been reported with systemic use Patients with Cockayne syndrome should report any symptoms of potential liver injury to their physician and stop taking metronidazole
- If a liver function test must be performed throughout treatment until liver function is within normal range
- If liver function is elevated during treatment , metronidazole should be discontinued
- Metronidazole has anti- treponemal activity and may mask the immune response seen in untreated syphilis
- Contacts of syphilis receiving metronidazole should be probably be screened for an additional 4 to 8 weeks.
- If possibly after trichomonas vaginalis has been eliminated a gonococcal infection might persist
- Alcohol beverages and medicines containing alcohol should not be consumed during therapy and at least 1 to 3 days afterwards. (see taking BEMETRAZOLE with food and drink)
- If pseudomembranous colitis (infection of the colon) has been reported with the use of BEMETRAZOLE.

- Co-administration with busulfan (treatment for cancer of blood cells) may lead to severe busulfan toxicity and death.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before receiving BEMETRAZOLE. Do this even if they have applied in the past.

Other medicines and BEMETRAZOLE

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

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

Disulfiram for the treatment of alcoholism. Taking BEMETRAZOLE with disulfiram can result in acute confusion.

Alcohol or medicine containing alcohol (see Taking BEMETRAZOLE with food and drink).

Medicines used to thin the blood such as warfarin. BEMETRAZOLE intensifies the effect of warfarin and may result in uncontrolled bleeding.

Lithium for mental illness. Blood levels of lithium may be increased by BEMETRAZOLE.

Phenytoin or phenobarbital for epilepsy reduce the effectiveness of BEMETRAZOLE.

5-Fluorouracil for cancer. BEMETRAZOLE may intensify the of harmful effects of 5-fluorouracil.

Busulfan for leukaemia (cancer of the blood cells) (see Take special care with BEMETRAZOLE).

Ciclosporin to prevent the rejection of organs after transplant. BEMETRAZOLE may increase the blood levels of ciclosporin.

Cimetidine for stomach ulcers may intensify the effects of BEMETRAZOLE

Taking BEMETRAZOLE with food and drink:

Do not drink any alcohol while you are having BEMETRAZOLE and for 1 to 3 days after

finishing your course. Drinking alcohol whilst you are being treated with BEMETRAZOLE might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pains, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

Pregnancy, breastfeeding and fertility:

The safety of BEMETRAZOLE in pregnancy and breastfeeding has not been established.

If you are pregnant or breast feeding your baby while taking

BEMETRAZOLE, please consult your doctor, pharmacist or other health care professional for advice

Tell your doctor before using BEMETRAZOLE if:

-You are pregnant, might become pregnant or think you may be pregnant, or you are breastfeeding. This is because small amounts of BEMETRAZOLE may pass into the mother's milk.

Driving and using machinery:

While taking BEMETRAZOLE, you 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 version). If this happens, do not drive or use any machinery or tools.

BEMETRAZOLE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take BEMETRAZOLE:

Taking your medicine:

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

Always take BEMETRAZOLE exactly as your doctor has instructed you. It is important to finish a full course of treatment.

Check with your doctor or pharmacist if you are not sure.

The usual dose is as below:

Anaerobic infections

a) Treatment:

Metronidazole 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 and infants: 7,5 mg/kg body mass by mouth every 8 hours daily during or after meals

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. Shorter pre-operative courses and oral doses of up to 1 g have been used

Children: as for treatment (a).

Treatment of Helicobacter pylori-associated gastritis and duodenal ulcer

The following regimens have been used:

a) **BEMETRAZOLE** 200-250 mg – 4-5 times a day for 14 days in combination with other medicines

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 and length of your treatment will depend on the type and severity of your condition.

Your doctor will tell you how long your treatment with BEMETRAZOLE will last Do not stop treatment early because you are feeling well.If you have the impression that the effects of

BEMETRAZOLE is too strong or too weak, tell your doctor or pharmacist.

Tests:

Your doctor may wish to carry out some tests if you have been using BEMETRAZOLE for more than 10 days

If you take more BEMETRAZOLE 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. Take the carton and bottle with you. This is so the doctor knows what you have taken.

If you forget to take BEMETRAZOLE:

If you forget to take BEMETRAZOLE, 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

BEMETRAZOLE can have side effects.

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

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

- a serious but rare side effect is a brain disease (encephalopathy).Symptoms vary but you might get a fever, stiff neck, headache andsee or hear things that are not there. You might also have problems using your arms and legs, problems with speaking or feel confused.
- if you get swelling of the hands, feet, ankles, face, lips or throat, which may cause

difficult in swallowing or breathing. You could also notice an itchy, nettle rash (urticaria). This may mean that you are having an allergic reaction to BEMETRAZOLE.

- Fainting

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following side effects:

- yellowing of the skin and eyes. this could be due to a liver problem (jaundice)
- unexpected 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)

These are serious side effects .You may need urgent medical attention

Tell your doctor or pharmacist if you notice any of the following side effects:

Frequent side effects:

- 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)
- stomatitis (sore mouth, mouth ulcers and cold sores)

Less frequent side effects:

- 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
- weakness
- dizziness
- drowsiness
- skin rash
- headache
- darkening of the urine
- feeling sleepy or dizzy
- unable to sleep
- pseudomembranous colitis (watery and severe diarrhoea, which may also be bloody)

Frequency unknown side effects:

- low white blood cell count
- weight loss
- 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, stomach pain or diarrhoea
- loss of appetite
- fever
- feeling depressed
- pain in your eyes (optic neuritis)
- a group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. this may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)

- hearing impairment/hearing loss
- ringing in the ears (tinnitus)
- you get a rash or skin discolouration with or without raised areas which often reoccurs at the same location each time the drug is taken
- nasal congestion
- skin rashes
- pain in the joints
- pain in the muscles or group of muscle

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 or pharmacist or nurse. 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 BEMETRAZOLE.

5. How to store BEMETRAZOLE

- 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 BEMETRAZOLE contains

The active substance is metronidazole.

BEMETRAZOLE (200)

Each tablets contains: Metronidazole 200 mg

BEMETRAZOLE (400)

Each tablet contains: Metronidazole 400 mg

The other ingredients are:

Lactose monohydrate 200 mesh, magnesium stearate,

starch maize, pregelatinized starch, purified talc

What bemetrazole looks like and contents of the pack

BEMETRAZOLE (200)

Round biconvex tablets scored on one side

BEMETRAZOLE (400)

Round biconvex tablets scored on one side

BEMETRAZOLE 200 tablets: tablets are packed in securitainers in 21's,100's or 500's

Patient ready packs of different pack sizes.

BEMETRAZOLE (400) **tablets**: tablets are packed in securitainers in 10's,100's or 500's as well as 500's in HDPE containers

Patient ready packs of different pack sizes.

Holder Of Certificate Of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

This Leaflet Was Last Revised In

13 January 2022

Registration Number(S)

South Africa

BEMETRAZOLE (200)**:** 29/20.2.6/0745

BEMETRAZOLE (400): X/20.2.6/84

Namibia:

BEMETRAZOLE (200) NS2 Reg. No.: 04/20.2.6/0097 (500's)

BEMETRAZOLE (400)**:** NS2 Reg. No.: 90/20.2.6/00362

(10's;100's & 500's)

Botswana:

Botswana List No.: B9314815 for Bemetrazole 400 mg (100`s & 500`s)