PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAMES, STRENGTH AND PHARMACEUTICAL FORMS:

SANDOZ® ETHAMBUTOL HCl 100 (tablets)

SANDOZ® ETHAMBUTOL HCl 400 (tablets)

Read this entire leaflet carefully before you start taking SANDOZ ETHAMBUTOL HCl.

- 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.
- SANDOZ ETHAMBUTOL HCl 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.

1. WHAT SANDOZ ETHAMBUTOL HCl CONTAINS:

SANDOZ ETHAMBUTOL HCl 100 and 400 tablets contain ethambutol hydrochloride 100 mg and 400 mg respectively as the active ingredient.

SANDOZ ETHAMBUTOL HCl 100 also contains the following inactive ingredients:

Acacia, hydroxypropylmethylcellulose, lactose 200 mesh, magnesium stearate, maize starch, sucrose fine, purified talc.

Contains sugar (lactose 215,00 mg and sucrose 20,00 mg per tablet).

SANDOZ ETHAMBUTOL HCl 400 also contains the following inactive ingredients:

Black TF powder, lactose 200 mesh, magnesium stearate, maize starch, povidone K30.

Contains sugar (lactose 148,18 mg per tablet).

2. WHAT SANDOZ ETHAMBUTOL HCl IS USED FOR:

SANDOZ ETHAMBUTOL HCl is used for the treatment of tuberculosis (TB) together with other medicines.

3. BEFORE YOU TAKE SANDOZ ETHAMBUTOL HCl:

Do not take SANDOZ ETHAMBUTOL HCl if:

- You are allergic to ethambutol or any of the other ingredients in the tablets (see “WHAT SANDOZ ETHAMBUTOL HCl CONTAINS”)
- If you have sight problems caused by inflammation of nerves in your eye (optic neuritis).

Take special care with SANDOZ ETHAMBUTOL HCl:

Talk to your doctor or pharmacist before taking SANDOZ ETHAMBUTOL HCl if:

- You have problems with your eyes or vision. If you should develop problems with your vision while using SANDOZ ETHAMBUTOL HCl, you should immediately stop using this medicine and notify your doctor immediately.
- Your kidney function is impaired.

Taking SANDOZ ETHAMBUTOL HCl with food and drink:

The tablets should be swallowed whole with a glass of water. If you feel nauseous or your stomach burns when you take SANDOZ ETHAMBUTOL HCl, it is recommended that you take this medicine with food.

Pregnancy and breastfeeding:

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

You should not take this medicine if you are pregnant, breastfeeding or trying for a baby without consulting your doctor first.

Driving and using machinery:

If you suffer from blurred vision, headaches or confusion after using SANDOZ ETHAMBUTOL HCl, make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired.

Important information about some of the ingredients of SANDOZ ETHAMBUTOL HCl:

SANDOZ ETHAMBUTOL HCl contains lactose and sucrose. Patients with the rare hereditary conditions of lactose/fuctose or galactose intolerance should not take SANDOZ ETHAMBUTOL HCl.

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

SANDOZ ETHAMBUTOL HCl contains lactose and sucrose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with SANDOZ ETHAMBUTOL HCl:

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

If you are taking other medicines on a regular basis including complementary medicines together with SANDOZ ETHAMBUTOL HCl, it may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice if you are taking any of the following medication:

- Medicine for convulsion like carbamazepine.
- Antibiotics such as chloramiphenicol, tetracyclines, ciprofloxacin and metronidazole.
- Methotrexate (for e.g. used for arthritis).
- Diuretics such as pyrazinamide.

You should not take ethambutol tablets at the same time as antacid medicine containing aluminium hydroxide (used to treat heartburn and indigestion) as this can make ethambutol less effective.

4. HOW TO TAKE SANDOZ ETHAMBUTOL HCl:

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

Always take SANDOZ ETHAMBUTOL HCl exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

It is important to keep taking your medicine for as long as your doctor prescribes them.

Do not stop taking your medicine without consulting your doctor first.

Your doctor or health care professional will decide the correct dosage for your specific condition.

The tablets should be swallowed whole with a glass of water at the same time every day.

Adults:

The dosage will be 15 to 25 mg of SANDOZ ETHAMBUTOL HCl per kg of body weight once a day.

Children:

The usual dose of ethambutol for children above three months is 15 to 25 mg per kg of body weight per day.

If you take more SANDOZ ETHAMBUTOL HCl than you should:

In the event of an over dosage you could experience the following symptoms:

Visual disturbance, hallucinations and abdominal pains. In the event of an over dosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison control centre **immediately**. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your SANDOZ ETHAMBUTOL HCl tablets:

If you forget to take a dose, take it as soon as you remember. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

SANDOZ ETHAMBUTOL HCl can have side effects.

The possible side effects are:

- Allergic reactions including skin rash and itching.
- Breathing problems.
- Reduction in certain types of blood cells which may cause an increased risk of infection.
- Dizziness, confusion, disorientation, headache, hallucination.
- Gut and stomach problems such as loss of appetite, feeling or being sick, diarrhoea, metallic taste, weight loss, wind or stomach pain.
- Severe skin conditions with blistering of the skin, mouth, eyelids and genitals or peeling skin.
- Numbness, pins and needles, weakness, burning pain, shaking.

- Gout, signs of which are, pain or swelling in your joints (especially big toe) with tender hot skin over effected joints.
- Skin problems including hard lumps or red patches often on the backs of arms and hands.
- Reduced blood platelets which can cause a purple rash, prolonged bleeding after injury or bruising easily.
- Liver problems, which may result in pale stools, dark urine, or make your skin or eyes look slightly yellow.
- Abnormal blood test results for liver function or urea concentration.

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

Tell your doctor if you experience or notice any of these side effects mentioned in this leaflet; they will discuss ways of managing or reducing the symptoms.

6. STORING AND DISPOSING OF SANDOZ ETHAMBUTOL HCl TABLETS:

- Store at or below 25 °C.
- Keep the containers in which the tablets are stored well closed.
- Do not store tablets in the bathroom.
- Do not use SANDOZ ETHAMBUTOL HCl after the expiry date printed on the label or carton.
- Return the expired medicine to your pharmacist for safe disposal.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

7. PRESENTATION OF SANDOZ ETHAMBUTOL HCl:

SANDOZ ETHAMBUTOL HCl 100 and 400 tablets are supplied in amber glass bottles, plastic securitainers or blister strip packs containing 28, 40, 56, 60, 84, 100 or 500 tablets.

Not all pack sizes are necessarily marketed.

8. IDENTIFICATION OF SANDOZ ETHAMBUTOL HCl:

SANDOZ ETHAMBUTOL HCl 100 is a white to off-white, round, slightly mottled, biconvex tablets.

SANDOZ ETHAMBUTOL HCl 400 is a bluish-grey green, round, slightly mottled, biconvex tablet.

9. REGISTRATION NUMBERS:

SANDOZ ETHAMBUTOL HCl 100: Q/20.2.3/175

SANDOZ ETHAMBUTOL HCl 400: Q/20.2.3/176

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

Waterfall 5lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

11. DATE OF PUBLICATION:

Date on the registration certificate of the medicine: 20 June 1983

Date of most recent approval of patient information leaflet: 22 August 2019