1.5.5 Proposed Clean Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

ZOTHENA 4 mg, 4 mg orodispersible tablets

ZOTHENA 8 mg, 8 mg orodispersible tablets

Ondansetron

Contains sugar:

ZOTHENA 4 mg: Each orodispersible tablet contains 167,14 mg mannitol.

ZOTHENA 8 mg: Each orodispersible tablet contains 334,28 mg mannitol.

Contains artificial sweetener:

ZOTHENA 4 mg: Each orodispersible tablet contains 3 mg aspartame.

ZOTHENA 8 mg: Each orodispersible tablet contains 6 mg aspartame.

Read all of this leaflet carefully before you start taking ZOTHENA

- 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.
- **ZOTHENA** 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 is **ZOTHENA** and what it is used for

2. What you need to know before you take **ZOTHENA**

3. How to take **ZOTHENA**

4. Possible side effects

5. How to store **ZOTHENA**

6. Contents of the pack and other information

1. What is ZOTHENA and what it is used for

EUROTON contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. **ZOTHENA** orodispersible tablets are a special type of tablets that dissolves very quickly when put on top of the tongue.

ZOTHENA is used for:

- preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer
- preventing nausea and vomiting after surgery.

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. What you need to know before you take ZOTHENA

Do not take ZOTHENA:

- if you are hypersensitive (allergic) to ondansetron or any of the other ingredients of **ZOTHENA** (listed in section 6).
- if you are taking apomorphine (used to treat Parkinson's disease)
- if you are pregnant, especially during the first 12 weeks, as your baby may develop an oral cleft palate and/ or lip
- post-operative nausea and vomiting in pregnancy

- if you have been diagnosed with a cardiac condition called congenital long QT syndrome.

Warnings and precautions

Talk to your doctor or pharmacist before taking **ZOTHENA**. Special care should be taken with **ZOTHENA**:

- if you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- if you have an uneven heartbeat (arrhythmias)
- if you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- if you suffer from myocardial ischemia (a condition where blood flow to the heart muscle is obstructed by a partial or complete blockage of a coronary artery due to a build-up of plaques (atherosclerosis).
- if you have problems with the levels of salts in your blood (seen from blood tests), such as potassium, sodium and magnesium.
- if you are taking medicines called serotonergic medicines, used to treat mental health conditions.
- if you have a blockage in your gut
- if you are going to have or have had a procedure called adenotonsillar surgery.
- if you have been diagnosed with a condition called phenylketonuria.

Liver damage

If you suffer from moderate or severe liver disease, the daily dose of 8 mg should not be exceeded, as **ZOTHENA** takes longer to break down and leave your body.

Children

Children recieving chemotherapy that affects the liver must be closely monitored.

Other medicines and ZOTHENA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) This is because **ZOTHENA** can affect the way some medicines work. Also, some other medicines can affect the way **ZOTHENA** works.

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

- cancer medicines (especially anthracyclines and trastuzumab)
- antimicrobials such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heartbeat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine
- apomorphine used to treat Parkinson’s disease
- carbamazepine or phenytoin used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- tramadol, a pain killer.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have

a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **ZOTHENA**.

You should not take **ZOTHENA** if you are pregnant.

Women of childbearing potential should consider the use of contraception.

Do not breast-feed if you are taking **ZOTHENA**. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Driving and using machines

ZOTHENA may affect your ability to drive or operate machines and caution is advised until the effects of **ZOTHENA** on treatment are known.

It is not always possible to predict to what extent **ZOTHENA** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **ZOTHENA** affects you.

ZOTHENA contains aspartame

This medicine contains aspartame (which is a source of phenylalanine). If you have an inherited illness called phenylketonuria speak to your doctor before taking this medicine.

3. HOW TO TAKE ZOTHENA

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

Always take **ZOTHENA** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

To prevent nausea and vomiting from chemotherapy or radiotherapy

For adults, on the day of chemotherapy or radiotherapy

- The usual adult dose is 8 mg orally, taken one or two hours before treatment, followed by 8 mg every twelve hours.

For adults, on the following days

- The usual adult dose is 8 mg twice a day
- This may be given for up to 5 days.

When there is very severe nausea and vomiting caused by chemotherapy, ondansetron injections may be given at first, followed by **ZOTHENA** 8 mg twice a day for up to 5 days.

For children:

Ondansetron injections may be given at first, followed by **ZOTHENA** 4 mg twice a day for up to 5 days.

To prevent nausea and vomiting after an operation

Adults

The usual adult dose is 16 mg before your operation before the anesthetic is given.

Children

It is recommended that ondansetron is given as an injection.

Method of administration

Place the tablet on top of the tongue, where it will dissolve within seconds, then swallow.

If you take more ZOTHENA than you should

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

Symptoms of overdose may include visual disturbances, severe constipation, heart rhythm problems, low blood pressure and fainting.

If you forget to take ZOTHENA

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

4. POSSIBLE SIDE EFFECTS

ZOTHENA can have side effects.

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

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

Serious allergic reaction. The signs may include:

- sudden wheezing and chest pain or chest tightness
- shortness of breath
- low blood-pressure
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- collapse

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- a feeling of warmth or flushing
- constipation

Less frequent side effects:

- siezures or unusual body movements or shaking
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)
- irregular heartbeat
- chest pain
- low blood pressure, which can make you feel faint or dizzy
- hiccups
- changes to liver function test results (if you take **ZOTHENA** with a medicine called cisplatin, otherwise this side effect is uncommon).

Frequency unknown

- Myocardial ischemia (symptoms include sudden chest pain or chest tightness, neck or jaw pain, shoulder or arm pain, fast heartbeat, shortness of breath, sweating and tiredness).

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 **ZOTHENA**.

5. HOW TO STORE ZOTHENA

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package / container.
- **ZOTHENA** should only be taken out of the blister immediately before taking it.
- Do not use this medicine 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).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ZOTHENA contains

- The active substance is ondansetron.
- The other ingredients are aspartame, basic butylated methacrylate copolymer, crospovidone, magnesium stearate, mannitol, mannitol granular, silica colloidal anhydrous, strawberry flavour.

What ZOTHENA looks like and contents of the pack

ZOTHENA tablets are round white to off-white, flat, bevelled edged tablets, plain on both the

surfaces, having strawberry odour, packed in aluminium-aluminium blister.

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

Woodmead Office Park,

3 Stirrup Lane, Van Reenens Avenue,

Woodmead,

2144

This leaflet was last revised in

December 2022

Registration Number

Zothena 4 mg: 52/5.10/1010

Zothena 8 mg: 52/5.10/1011