PATIENT INFORMATION LEAFLET

NECTIZOLE 20 & NECTIZOLE 40

SCHEDULING STATUS **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NECTIZOLE 20 gastro-resistant tablet

NECTIZOLE 40 gastro-resistant tablet

Read all of this leaflet carefully before you start taking NECTIZOLE.

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

The active substance is esomeprazole.

Each **NECTIZOLE 20** tablet contains 20 mg esomeprazole (as esomeprazole magnesium dihydrate).

Each **NECTIZOLE 40** tablet contains 40 mg esomeprazole (as esomeprazole magnesium dihydrate).

The other ingredients are listed below in alphabetical order, coating materials included.

Crospovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, macrogol 6000, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, polysorbate, povidone, sodium stearyl fumarate, sugar spheres (consisting of maize starch and sucrose), talc, triethyl citrate, Opadry Pink (consisting of hypromellose, iron oxide red, iron oxide yellow, macrogol, titanium dioxide).

2. WHAT NECTIZOLE IS USED FOR

NECTIZOLE contains esomeprazole, which belongs to a group of medicines called proton pump inhibitors. Esomeprazole acts on the gastrointestinal tract and decreases the amount of acid that your stomach produces.

NECTIZOLE may be used to:

- treat the symptoms of heartburn that you experience with acid that pushes up from your stomach into your oesophagus (gullet), called gastro-oesophageal reflux disease (GORD);
- treat (together with antibiotics), or to prevent, gastric or duodenal ulcers caused by infection with a micro-organism, called *Helicobacter pylori;*
- to prevent sores in the stomach or the first part of the small intestine if you use nonsteroidal anti-inflammatory drugs (NSAIDs), or
- certain inherited conditions where your stomach produces too much acid, for example the Zollinger-Ellison syndrome.

3. BEFORE YOU TAKE NECTIZOLE

Do not take NECTIZOLE if you:

- are hypersensitive (allergic) to esomeprazole or other medicines called benzimidazoles, or any of the other ingredients of NECTIZOLE;

- are taking medicines called atazanavir or nelfinavir (antiretroviral medicines used to treat human immunodeficiency virus (HIV)).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist or professional healthcare provider.

Take special care with NECTIZOLE

The presence of other medical problems may affect the use of NECTIZOLE. NECTIZOLE may hide symptoms of other diseases, therefore it is important to talk to your doctor, pharmacist or healthcare professional before taking NECTIZOLE and during the use of NECTIZOLE if you:

- vomit frequently, have stomach pain, indigestion or have lost a lot of weight without reason and have problems swallowing or if you pass dark stools (may contain blood);
- have osteoporosis (a bone disorder where you lose bone mass), as you may break your hip, wrist and spine more easily if you take NECTIZOLE for a long time;
- take digoxin (a heart medicine) or diuretics (water tablets), as you may develop a serious shortage of magnesium in your blood; and
- have serious liver problems, as your doctor may want to lower your dosage.

You should know that taking NECTIZOLE may mask the symptoms of gastric cancer, it is therefore important that you tell your doctor about any of the above symptoms, or other symptoms that you are concerned about.

NECTIZOLE suppresses the acid in your stomach. This may cause the number of *Clostridium difficile* bacteria (germs) present in your gut to increase greatly and to produce toxins (poisons) that affect your small and large bowels. Tell your doctor immediately if you get a fever as well as stomach pain and a very runny tummy with watery stools. Do not treat yourself to stop such loose bowel movements; speak to your doctor.

Taking NECTIZOLE for a long time, may cause cysts (a closed sac that contains fluid or semisolid material) in the glands of your stomach. Make sure that you keep to your regular follow-up appointments with your doctor while you take NECTIZOLE. He/she will tell you if you need any further diagnostic procedures.

Taking NECTIZOLE with food or drink

You should take NECTIZOLE on an empty stomach (at least 30 minutes before you eat). Only take NECTIZOLE with water (see **HOW TO TAKE NECTIZOLE**).

Pregnancy and breast-feeding

NECTIZOLE should not be used if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking NECTIZOLE.

Driving and using machinery

If NECTIZOLE causes you to become dizzy or have blurred vision, you should not drive or handle dangerous tools.

Important information about some of the ingredients of NECTIZOLE

NECTIZOLE 20 contains about 5,65 mg sugar (as sucrose), and NECTIZOLE 40 about 11,3 mg sugar (as sucrose), per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NECTIZOLE.

Taking other medicines with NECTIZOLE

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

Also tell your doctor, pharmacist or other healthcare professional if you are using or receiving any of the following medicines:

- Atazanavir or nelfinavir (antiretroviral medicines used to treat HIV).
- Ketoconazole, itraconazole or voriconazole (medicines used to treat fungal infections such as thrush, ringworm).
- Diazepam, imipramine, clomipramine, citalopram and certain other medicines used for anxiety, depression or muscle spasms.
- Phenytoin (used in epilepsy). Your doctor may monitor your blood closely to check on the phenytoin levels when you start or stop taking NECTIZOLE.
- Cisapride (used for indigestion and heartburn).
- Digoxin (heart medicine).
- Iron supplements.
- NSAIDs (nonsteroidal anti-inflammatory drugs), used for pain and inflammation.
- Medicines to prevent blood clots such as warfarin and clopidogrel.
- Methotrexate (a medicine used for cancer or severe rheumatic conditions).
- Rifampicin (an antibiotic that may be used for tuberculosis (TB)).
- St John's wort (a herbal medicine that may be used for depression).

NECTIZOLE may prevent accurate diagnoses with some laboratory tests and procedures. Always tell your doctor or healthcare professional that you are taking NECTIZOLE.

If your doctor has prescribed amoxicillin and clarithromycin together with NECTIZOLE to treat ulcers caused by an infection with *Helicobacter pylori* (a germ), it is also very important that you tell your doctor about all other medicines that you are taking, including those that you have obtained yourself.

Before you begin using any new medicine (prescription or non-prescription), consult with your doctor, pharmacist or healthcare professional for advice.

4. HOW TO TAKE NECTIZOLE

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

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

NECTIZOLE is not intended for immediate relief of symptoms caused by heartburn.

- **Children below 12 years:**

NECTIZOLE is not recommended for children younger than 12 years of age.

- **Adults and children above 12 years:**

The usual dose is:

Your doctor will tell you which dose is suitable for you and for how long you should continue. Usually you will take your NECTIZOLE tablets as follows:

For serious heartburn caused by gastro-oesophageal reflux disease (GORD):

Usually, the dose is 1 x NECTIZOLE 40 gastro-resistant tablet once a day for 4 weeks at first, after which your doctor will decide if you should continue for another 4 weeks at the same dosage or not.

Once your gullet has healed sufficiently, or if it is not damaged, your doctor may prescribe a dosage of 1 x NECTIZOLE 20 tablet per day for long-term management of your gastro-oesophageal reflux disease.

To prevent stomach ulcers if you are taking NSAIDs:

The usual dose is 1 x NECTIZOLE 20 or 1 x NECTIZOLE 40 gastro-resistant tablet once a day.

To treat ulcers caused by Helicobacter pylori infection and to stop recurrence:

The usual dose is 1 x NECTIZOLE 20 gastro-resistant tablet twice a day for one week. Your doctor may instruct you to simultaneously take antibiotics such as amoxicillin and clarithromycin.

If you have Zollinger-Ellison syndrome (see **WHAT NECTIZOLE IS USED FOR**), the usual dose is 1 X NECTIZOLE 40 tablet twice a day. Your doctor may prescribe a higher dose.

Liver disorders:

If you have liver problems, your doctor may want you to use a lower dose.

Elderly persons:

No special dosage is necessary if you are elderly (above 65 years).

How to take your tablets

Swallow your tablets whole, with a drink of water.

You can take NECTIZOLE at any time of the day, at least 30 minutes before a meal.

Do not chew or crush the tablets, as the tablets consist of coated pellets which must not be damaged. These pellets are individually coated to ensure that the medicine is not broken down by the acid in your stomach.

- **If you have trouble swallowing the whole tablets:**

If you have difficulty in swallowing, the tablets can also be stirred in half a glass of non-carbonated water. Stir until the tablets disintegrate (the mixture will not be clear) and drink the water with the pellets immediately. No other liquids should be used, as the enteric coating on the pellets may dissolve. Rinse the glass with a little more water and finish it immediately. Do not chew these particles.

- **If you cannot swallow:**

The tablet can be mixed with some water and can be put into a syringe which is emptied into a gastric tube for direct administration into your stomach.

Your doctor will tell you how long your treatment with NECTIZOLE will last. Do not stop treatment early, as your symptoms may recur.

If you have the impression that NECTIZOLE is too strong or too weak, you should talk to your doctor or pharmacist.

If you take more NECTIZOLE 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 this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

Although signs of overdosage differ, you may possibly feel weak and have tummy problems (loose bowels and abdominal pain) and feel sick (nauseous).

If you forget to take a dose of NECTIZOLE

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

Effects when treatment with NECTIZOLE is stopped

Talk to your doctor before you stop taking NECTIZOLE, as your symptoms may recur.

5. POSSIBLE SIDE EFFECTS

NECTIZOLE can have side effects.

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

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

- Swelling of the lips, face and eyes, abdominal pain, vomiting (being sick), difficulty breathing, wheezing or coughing (anaphylaxis) or swelling below the skin with red welts, burning, painful sometimes itchy skin areas, tight throat (angioedema).

These are all very serious side effects. If you have them, you may have a serious, potentially life-threatening allergic reaction to NECTIZOLE. 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 the following:

- Symptoms of the flu, including cough, fever and headache, followed by a painful rash that spreads and forms blisters. The blisters cause the affected skin to die and shed. The disease may leave the skin looking burned. These signs may be due to the Stevens-Johnson syndrome (a serious, sometimes fatal inflammatory disease).
- Yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice), or nausea, vomiting, loss of appetite, abdominal pain, dark urine, light coloured stools, tiredness (hepatitis with or without jaundice).
- Fever and infections – you may have leukopenia, agranulocytosis or pancytopenia (a severe reduction in number of white blood cells). Your doctor will order blood tests and treat you suitably.
- Blood in the urine, fever, nausea, swelling, increased or decreased urine output. You may have inflammation in the kidneys (interstitial nephritis). The inflammation can affect the kidneys' function, including their ability to filter waste. If you think you have this, call your doctor who will tell you what to do.
- Runny tummy with watery stools, fever and stomach pains. See **Take special care with NECTIZOLE**.

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

Tell your doctor if you notice any of the following:

Frequently occurring side effects:

- Headache.

- Pain on the belly, diarrhoea, constipation, wind, nausea or vomiting (being sick).

Less frequently occurring side effects:

- Thrush (white spots due to yeast infection) with pain and inflammation (red tissue) in the mouth, gut or gullet. Your doctor may prescribe antifungal medicine if you have this disorder.
- Bruising easier and excessively, purple spots in skin, prolonged bleeding from cuts, spontaneous bleeding from nose or gums. You may have thrombocytopenia (a low blood platelet count). Your doctor will order blood tests and treat you suitably.
- Swelling of the feet and ankles.
- Increased sweating.
- Feeling weak, sick and having muscle cramps may be a sign that you have low blood sodium (hyponatraemia).
- Problems with sleeping (insomnia) or sleepiness, feeling agitated, confused or depressed, feeling aggressive; seeing, feeling or hearing things that are not there (hallucinations).
- Taste changes, dizziness, tingling of hands and/or feet – “pins and needles”.
- Eyesight affected: blurred vision.
- Middle ear balance disorder.
- Breathing problems; feeling wheezy or short of breath.
- Dry mouth.
- Skin rash and skin sensitive for sunlight, lumpy rash (hives) and itching, hair loss.
- Joint pains or muscle pains; muscle or bone weakness which may possibly make it easier to break your wrist, spine and hip if you are injured.
- Enlarged breasts in men.
- Feeling unwell and lacking energy, sweating more than usually.

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

6. STORING AND DISPOSING OF NECTIZOLE

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place in the original packaging. Keep blisters in the carton until required for use. Keep container tightly closed.

Do not store in a bathroom.

Do not use NECTIZOLE after the expiry date printed on the carton and on the blister. Return all unused or expired medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF NECTIZOLE

NECTIZOLE 20 and NECTIZOLE 40 gastro-resistant tablets are packed in one of the following packaging materials, in packs containing 14, 28 or 30 tablets:

- Blister strips consisting of a silver coloured plain aluminium foil and silver coloured cold forming blister aluminium foil (Alu/Alu blister) in an outer carton.
- Blister strips consisting of a silver coloured plain aluminium foil and clear colourless PVC/PVDC foil in an outer carton.
- White round HDPE containers with a desiccant, and closed with white round LDPE lids in an outer carton.

Not all pack sizes are necessarily marketed at any one time.

8. IDENTIFICATION OF NECTIZOLE

NECTIZOLE 20: Light pink coated 6,55 x 13,6 mm, elliptically shaped, biconvex gastro-resistant tablet.

NECTIZOLE 40: Pink coated 8,2 x 17 mm, elliptically shaped, biconvex gastro-resistant tablet.

9. REGISTRATION NUMBERS

NECTIZOLE 20: 48/11.4.3/0438

NECTIZOLE 40: 48/11.4.3/0439

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Activo Health (Pty) Ltd

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South Africa

11. DATE OF PUBLICATION

Pending