Clean Proposed Patient Information Leaflet for Medicines for Human Use: TUMSIGON

SCHEDULING STATUS: S4

TUMSIGON 20 mg capsules

Omeprazole

Contains sugar

Each TUMSIGON capsule:

Contains sucrose 165,95 mg and lactose anhydrous 2,99 mg.

Contains sweetener mannitol 55,90 mg.

Read all of this leaflet carefully before you start taking TUMSIGON

- 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.
- TUMSIGON 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 TUMSIGON is and what it is used for

TUMSIGON contains the active substance omeprazole. It belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

TUMSIGON is used to treat the following conditions:

Adults

- Ulcers (sores that are slow to heal or keep returning) in the lining of the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Reflux oesophagitis and gastroesophageal reflux disease (GERD), where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Indigestion (dyspepsia).
- Zollinger-Ellison Syndrome, when excess stomach acid are produced due to a growth in the pancreas.
- Duodenal ulcers which are infected with bacteria called “*Helicobacter pylori*”. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Gastric and/or duodenal ulcers caused by medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- For reducing the risk of developing ulcers in patients taking NSAIDs and in patients who have previously had an ulcer and need to continue therapy with a NSAID. In such patients, TUMSIGON can prevent an ulcer developing by protecting the stomach or duodenum (first part of small intestine) whilst they are taking NSAIDs.

Children

- For the short-term treatment (up to 3 months) of severe ulcerative reflux oesophagitis, which has not responded to previous medical treatment. Severe ulcerative reflux oesophagitis is an

inflammation of the oesophagus (gullet), including the development of ulcers on the lining of the gullet, caused by stomach acid flowing back into the gullet.

2. What you need to know before you take TUMSIGON

Do not take TUMSIGON

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of TUMSIGON (listed in section 6).
- If you are allergic to medicines that have a benzimidazole in their structure such as other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are pregnant or breastfeeding.
- if you are taking a medicines called nelfinavir and atazanavir (used for HIV infection).

Warnings and precautions

Take special care with TUMSIGON

TUMSIGON may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking TUMSIGON, or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing
- You get stomach pain or indigestion
- You begin to vomit food or blood
- You pass black, tarry stools (blood-stained faeces)

Tell your doctor if you:

- experience severe or persistent diarrhoea, as TUMSIGON has been associated with an increased risk of infectious diarrhoea
- have kidney problems as TUMSIGON can cause a type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including

TUMSIGON, may develop a kidney problem called acute nephritis that can happen at any time during treatment with TUMSIGON. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.

- are taking a medicine called atazanavir or nelfinavir (see Section 2, Do not take TUMSIGON)
- have liver problems, therefore your doctor may want to reduce your dose
- are taking a medicine called clopidogrel (used to prevent blood clots)
- suffer from a condition called osteoporosis (weak bones which are easily broken) or if you are taking a medicines called corticosteroids (which can increase the risk of osteoporosis). Taking a proton pump inhibitor like TUMSIGON, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine
- suffer from symptoms of low magnesium levels such as tiredness, involuntary muscle contractions, metal confusion, convulsions (fits), dizziness, disturbances in the heart rate. Taking TUMSIGON for more than three months may lower the levels of magnesium in your blood. Your doctor may want to measure your magnesium levels before starting treatment with TUMSIGON or decide to perform regular blood tests during treatment to monitor your levels of magnesium, especially if you are taking a medicine called digoxin or other medicines that decrease your magnesium levels (e.g. diuretic medicines also called water pills).
- get a rash or skin reaction, especially after being exposed to the sun, after treatment with TUMSIGON. Sometimes the rash or skin reaction can be accompanied by other ill-effects like pain in your joints. Tell your doctor as soon as you can, as you may need to stop your treatment with TUMSIGON
- have a problem with Vitamin B_{12} levels in your body
- start suffering from stomach infections and runny tummy (diarrhoea) that does not improve.
- are due to have a specific blood test (Chromogranin A) used to diagnose tumours arising from neuroendocrine cells (nerve cells that receive messages (signals) from the nervous system and respond by making and releasing hormones). TUMSIGON treatment should be

stopped for at least 5 days before the blood test measurements are taken as it increases the Chromogranin A levels

- are taking methotrexate, a medicine used to treat cancer, rheumatoid arthritis and psoriasis
- are taking St. John's Wort, a medicine to treat mild depression
- are taking rifampicin an antibiotic to treat tuberculosis.

If you take TUMSIGON on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Children

There is only a limited amount of experience with the use of omeprazole, as in TUMSIGON in children. Some children with chronic illnesses may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 year of age or < 10 kg.

Other medicines and TUMSIGON

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

TUMSIGON may have effects on other medicine

TUMSIGON may weaken the effect of the following medicines

- Nelfinavir and atazanavir (used to treat HIV infection) – the blood levels may be decreased when taken together with TUMSIGON and may cause the HIV to become resistant to this HIV medicine and cause it to stop working effectively. You must not take TUMSIGON with nelfinavir and atazanavir.
- Clopidogrel (used to treat blood clots) – taking TUMSIGON capsules together with clopidogrel or 12 hours apart results in a lower concentration of clopidogrel in the blood,

thereby weakening the blood thinning effect and increasing the risk of blood clotting. You should not use TUMSIGON if you are taking medicine containing clopidogrel.

- Ketoconazole, itraconazole, posaconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).

TUMSIGON may strengthen the effect of the following medicines

- Digoxin (used to treat heart problems) – this may lead to digoxin poisoning. If you are elderly and/or taking high doses of digoxin your doctor may want to monitor your blood levels.
- Warfarin or other vitamin K blockers (used to thin the blood) – this may lead to excessive bleeding. Your doctor may need to take regular blood tests to check how well your blood can clot.
- Cilostazol (used to improve the symptoms of a certain blood flow problem in the legs e.g. pain in the legs that worsens when walking and improves when resting that is caused by narrowing of the blood vessels that supply blood to the legs).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy). This can cause you to fall into a deep sleep or experience blurred or double vision.
- Phenytoin (used to treat epilepsy) - Your doctor may need to take blood tests to check your phenytoin blood levels.
- Tacrolimus (used to prevent rejection of transplanted organs). Your doctor may need to take blood tests to check the tacrolimus concentrations in your blood and to check your kidney function (creatinine clearance) and then may adjust your dosage of tacrolimus if needed.
- Saquinavir (used to treat HIV infection).
- Methotrexate (used to treat certain types of cancer or to control severe psoriasis or rheumatoid arthritis). If you are taking a high dose of methotrexate, your doctor may temporarily stop your TUMSIGON treatment.

Other medicines may interact with TUMSIGON

The following medicines may increase the blood levels of omeprazole and strengthen the effect of TUMSIGON or lead to more unwanted side effects

- voriconazole (used to treat infections caused by a fungus)
- clarithromycin (an antibiotic used to treat bacterial infections)

The following medicines may decrease the blood levels of omeprazole and weaken the effect of TUMSIGON

- Rifampicin (used to treat tuberculosis)
- St John's wort (*Hypericum perforatum*) (a complementary medicine used to treat mild depression)

TUMSIGON with food and drink

You can take TUMSIGON capsules with food or on an empty stomach.

Swallow the capsules whole with a half glass of liquid.

Pregnancy and breastfeeding

Do not take TUMSIGON capsules if you are pregnant or 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 this medicine.

Driving and using machines

TUMSIGON capsules may cause sleepiness/drowsiness and affect your ability to concentrate. These side effects may be worsened by taking TUMSIGON capsules together with alcohol or other central nervous system depressants (medicines used to slow down brain activity and that may make you sleepy; such as cold or allergy medicine, sleeping pills, muscle relaxers, and medicines

for seizures, depression or anxiety). Other side effects such as dizziness, visual disturbances and vertigo (a sensation of feeling off balance) may occur (see section 4).

If you are affected, do not drive or use machinery.

Excipients sucrose and lactose

TUMSIGON contains the sugars sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Excipient mannitol

TUMSIGON contains the sweetener mannitol which, on rare occasions, may cause hypersensitivity reactions and may have a mild laxative effect.

3. How to take TUMSIGON

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

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

Dosage

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.

If you have the impression that the effect of TUMSIGON is too strong or too weak, tell your doctor or pharmacist.

Method of administration

- It is recommended that you take TUMSIGON capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow TUMSIGON capsules whole with half a glass of liquid.
- Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

If you take more TUMSIGON than you should

Symptoms of overdose may include blurred vision, confusion, excessive sweating, flushing (redness of skin), headache, general feeling of being unwell, nausea (queasiness, feeling that one is about to vomit), and increased heart rate can occur.

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

If you forget to take TUMSIGON

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose (two doses at the same time) to make up for a forgotten individual dose.

If you stop taking TUMSIGON

Do not stop taking TUMSIGON unless your doctor tells you to.

4. Possible side effects

TUMSIGON can have side effects.

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

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

- severe allergic reaction which causes sudden wheezing, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing or fainting
- severe skin rash, reddening of the skin with blisters or peeling, itching, or hives (elevated patches of red or pale skin that often itch) with flushing or ulcers and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (these are signs and symptoms of a very serious condition called Stevens-Johnson syndrome) or a severe rash with reddening and swelling that may lead to blistering and peeling of the skin and resembles burns (toxic epidermal necrolysis)
- liver inflammation (hepatitis), which may include jaundice which can cause yellow skin, dark urine and tiredness; liver failure leading to brain damage
- symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have bowel inflammation caused by a bacterial infection).

These are very serious side effects. If you have them, you may have had a serious reaction to TUMSIGON. 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:

- signs of infection, such as high temperature, chills, shivering, sore throat, mouth ulcers, headaches, sweating, flu-like symptoms or weakness, bleeding or bruising easily, pale skin and/or breathlessness. This may be the result of blood disorders (such as agranulocytosis (lack of white blood cells), neutropenia (lower-than-normal levels of neutrophils, a type of white blood cell) and pancytopenia (low counts for all three types of blood cells: red blood cells, white blood cells, and platelets)
- experiencing tiredness, a lack of energy and enthusiasm, intermittent muscular spasms or cramps, mental confusion, disorientation, sudden, violent, irregular, involuntary muscle contraction, dizziness and abnormal heart rhythms. These can be symptoms of low blood sodium and low blood magnesium (which may result in low blood calcium and/or blood potassium) and can happen if you are on TUMSIGON for more than three months. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium
- feeling nervous and irritable, confused, or depressed or aggressive
- seeing, feeling or hearing things that are not there (hallucinations)
- suddenly feeling wheezy or short of breath (bronchospasm)
- effects on your stomach or gut: Diarrhoea (If the diarrhoea is severe, it may be necessary to stop treatment with TUMSIGON), constipation, abdominal pain or colic, non-cancerous (benign) abnormal tissue growth (polyps) in the stomach
- yeast infections (called candidiasis or thrush) in the mouth, gullet or in the gut (intestines)
- changes in blood tests that check how the liver is working
- skin rash, itchy skin, lumpy rash (hives), skin sensitivity to light
- itchy skin rash with blood spots, bruising or discolouring of the skin leading to red patches characterised by bull's-eye-shaped lesions (erythema multiforme)
- osteoporotic bone fractures of the hip, wrist or spine (osteoporosis is a condition where certain bones become brittle), joint pains (arthralgia) or muscle pains (myalgia)

- decrease in urine volumes or if you suspect that there is blood your urine or if you are experiencing weakness, nausea and loss of appetite as this may be due to severe kidney problems (acute interstitial nephritis). This can lead to chronic renal failure if it is not diagnosed quickly. Your doctor will likely discontinue your treatment with TUMSIGON
- enlargement of breasts in men
- swelling of hands, ankles or feet (peripheral oedema)

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

Tell your doctor if you notice any of the following:

Frequent side effects

- trouble sleeping (insomnia)
- headache (If the headache is severe, it may be necessary to stop treatment with TUMSIGON)
- dizziness, tingling feelings such as “pins and needles”, feeling sleepy
- sensation of feeling off balance and that you, or the environment around you, is moving or spinning (vertigo)
- feeling sick (nausea), being sick (vomiting) or wind (flatulence)
- feeling of weakness, overall discomfort, illness, or simply not feeling well (malaise).

Less frequent side effects

- taste changes
- blurred vision
- dry mouth or an inflammation on the inside of the mouth
- hair loss
- increased sweating.

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. 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 TUMSIGON.

5. How to store TUMSIGON

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Keep the aluminium strip packs in the outer carton until required for use.
- Do not use TUMSIGON after the expiry date stated on the strip or carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What TUMSIGON contains

- The active substance is omeprazole. Each TUMSIGON capsule contains omeprazole 20 mg
- The other ingredients are

  Content

  Sugar pellets (consisting of sucrose and purified water)

  Mannitol

  Lactose anhydrous

Purified talc

Sodium lauryl sulfate

Povidone/Polyvinyl pyrrolidone (PVPK-30)

Anhydrous disodium hydrogen phosphate

Sucrose (sugar)

Hypromellose phthalate/Hydroxypropyl methylcellulose phthalate (HPMCP-55)

Cetyl alcohol

Titanium dioxide

Capsule shell

Gelatine

Methylparaben (preservative)

Propylparaben (preservative)

Cap - light blue

Brilliant blue (CI 42090)

Erythrosine (CI 45430)

Quinoline yellow (CI 47005)

Titanium dioxide (CI 77891)

Carmosine (CI 14720)

Body - dark blue

Brilliant blue (CI 42090)

Carmosine (CI 14720)

Erythrosine (CI 45430)

Quinoline yellow (CI 47005)

Titanium dioxide (CI 77891)

White printing ink

Absolute alcohol

Isopropyl alcohol

Shellac dewaxed powder

Titanium dioxide

What TUMSIGON looks like and contents of the pack

TUMSIGON is a size 2 hard gelatin capsules with a dark blue body and a light blue cap, containing white to almost white uniformly rounded enteric-coated pellets. "TUMSIGON" is printed on both the shells with white ink.

TUMSIGON is supplied as

6 capsules in aluminium strip pack:

5 of these strips in one carton i.e. 30 capsules pack.

7 capsules in aluminium strip pack:

4 of these strips in one carton i.e. 28 capsules per pack.

10 capsules in aluminium strip pack:

3 of these strips in one carton i.e. 30 capsules per pack.

or 10 of these strips in one carton i.e. 100 capsules per pack.

14 capsules in aluminium strip pack:

1 of these strips in one carton i.e. 14 capsules per pack

or 2 of these strips in one carton i.e. 28 capsules per pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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South Africa

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To be allocated by the Authority

Registration number

To be allocated by the Authority