Approved Patient Information Leaflet for Medicines for Human Use:

GOMESIS 80 mg/ 125 mg/ Combi pack

SCHEDULING STATUS: S4

GOMESIS 80 mg CAPSULES

GOMESIS 125 mg CAPSULES

GOMESIS COMBI PACK (125 mg and 80 mg) CAPSULES

Aprepitant

Contains sugar

Each 80 mg capsule contains 80 mg sucrose

Each 125 mg capsule contains 125 mg sucrose

Read all of this leaflet carefully before you start taking GOMESIS

- 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.
- GOMESIS 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 GOMESIS is and what it is used for
2. What you need to know before you take GOMESIS
3. How to take GOMESIS
4. Possible side effects
5. How to store GOMESIS

6. Contents of the pack and other information

1. What GOMESIS is and what it is used for

GOMESIS belongs to a group of medicines called anti-emetics and antinauseants (effective against nausea and vomiting). The brain has a specific area that controls nausea and vomiting. GOMESIS works by blocking signals to that area, thereby reducing nausea and vomiting. GOMESIS capsules are used with other medicines to prevent nausea and vomiting caused by chemotherapy (cancer treatment) that are strong and moderate triggers of nausea and vomiting (such as cisplatin, cyclophosphamide, doxorubicin or epirubicin).

GOMESIS should not be used continuously for a long time (chronic use).

2. What you need to know before you take GOMESIS

Do not take GOMESIS

- if you are hypersensitive (allergic) to aprepitant or any of the other ingredients of GOMESIS (listed in section 6).
- with medicines containing pimozide (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions), cisapride (used for treating digestive problems).

Safety and effectiveness of GOMESIS in paediatric patients have not been established. GOMESIS should therefore not be given to children.

Warnings and precautions

Before treatment with GOMESIS, tell your health care provider if:

- you have liver disease because the liver is important in breaking down the medicine in the body. Your health care provider may therefore have to monitor the condition of your liver.

- you take warfarin, as you will be monitored more closely.
- you take hormonal contraceptives, as efficacy may be reduced during treatment with GOMESIS.

Children and adolescents

GOMESIS has not been adequately studied in children. Therefore, GOMESIS should not be given to children.

Other medicines and GOMESIS

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

Do not take GOMESIS with pimozide, terfenadine, astemizole or cisapride. Taking GOMESIS with these medications could result in serious or life-threatening problems (see 'Do not take GOMESIS' above).

Tell your doctor if you are taking other medicines such as:

- birth control medicines which can include birth control pills, skin patches, implants, and certain Intrauterine devices (IUDs) that release hormones may not work adequately when taken together with GOMESIS. Another or additional non-hormonal form of birth control should be used during treatment with GOMESIS and for up to 2 months after using GOMESIS,
- cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants),
- alfentanil, fentanyl (used to treat pain),
- quinidine (used to treat an irregular heartbeat),
- irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer),

- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
- warfarin, acenocoumarol (blood thinners; blood tests may be required),
- rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (used to treat depression and epilepsy),
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep),
- St. John's Wort (an herbal preparation used to treat depression),
- protease inhibitors (used to treat HIV infections),
- ketoconazole except shampoo (used to treat Cushing's syndrome when the body produces an excess of cortisol),
- itraconazole, voriconazole, posaconazole (antifungals),
- nefazodone (used to treat depression),
- corticosteroids (such as dexamethasone and methylprednisolone),
- anti-anxiety medicines (such as alprazolam),
- tolbutamide (a medicine used to treat diabetes).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

The safety and efficacy of GOMESIS in pregnancy has not been established. GOMESIS is not recommended during pregnancy unless clearly necessary.

For information regarding birth control, see 'Other medicines and GOMESIS'.

It is not known whether GOMESIS is excreted in human milk; therefore, breastfeeding is not recommended during treatment with this medicine. It is important to tell your health care provider if you or the child are breastfeeding or are planning to breastfeed before taking GOMESIS.

Driving and using machines

It should be taken into account that some people feel dizzy and sleepy after taking GOMESIS. If you feel dizzy or sleepy, avoid driving, riding a bicycle or using machines or tools after taking this medicine (see section 4).

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

GOMESIS contains sucrose

If you have been told by your health care provider that you have an intolerance to some sugars contact your health care provider before taking GOMESIS. Contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

GOMESIS contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take GOMESIS

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

Always take this medicine or give this medicine to the child exactly as your health care provider has told you. You should check with your health care provider if you are not sure. Always take GOMESIS together with other medicines, to prevent nausea and vomiting. Check with your health care provider if you are not sure.

The usual dose is

Day 1:

- one 125 mg capsule 1 hour before you start your chemotherapy session

and Days 2 and 3:

- one 80 mg capsule once daily in the morning.

Duration of administration

Your health care provider will tell you how long your treatment with GOMESIS will last. Do not stop treatment early. If you have the impression that the effect of GOMESIS is too strong or too weak, tell your health care provider.

Paediatric population

The safety and efficacy of the 80 mg and 125 mg capsules have not been demonstrated in children.

Method of administration

- For oral administration.
- You can take GOMESIS with or without meals
- Swallow the capsule whole with some liquid.

If you take more GOMESIS than you should

In the event of overdosage, consult your health care provider. If not available, contact the nearest hospital or poison centre.

If you forget to take GOMESIS

If you forget to take a dose, leave that dose out completely. Take your next dose at the right time and continue as before. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

GOMESIS can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your health care provider immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- allergic reactions, which may be serious, and may include hives, rash and itching and cause difficulty in breathing or swallowing (severe skin reactions called Stevens Johnson syndrome/toxic epidermal necrolysis). If you have an allergic reaction stop taking GOMESIS and call your health care provider right away
- severe skin reactions may occur.

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

Tell your health care provider if you notice any of the following:

Frequent side effects:

- loss of appetite,
- headache,
- hiccups,
- constipation, indigestion,
- tiredness,
- increased amount of liver enzymes in your blood.

Less frequent side effects:

- bacterial infection, fungal infection
- fever with increased risk of infection, lowering of red blood cells
- excessive thirst,
- anxiousness, euphoria (feeling of extreme happiness), disorientation
- dizziness, sleepiness,
- difficulty thinking, lack of energy, taste disturbance,
- eye discharge and itching,
- ringing in the ear,

- feeling like your heart is beating too hard or too fast, beating irregularly like skipping a beat, or fluttering, slow heartbeat, heart and blood vessel disease,
- hot flush/reddening of the face or skin,
- cough, mucus in back of throat, throat irritation, sneezing, sore throat,
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind, severe constipation, stomach ulcer, inflammation of the small intestine and colon, sores in mouth, bloating,
- acne, rash, sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin,
- muscle spasms, muscle weakness,
- increased painful or burning urination, frequent urination, passing more urine than normal, presence of sugar or blood in urine,
- weakness, generally feeling unwell,
- chest discomfort, swelling, change in the manner of walking,
- lowering of white blood cells, low sodium levels in the blood, weight loss

Side effects with frequency unknown:

- itching rash, a sudden outbreak of swollen, pale red bumps or plaques (wheals) on the skin (urticaria also known as hives).

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. 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 GOMESIS**.**

5. How to store GOMESIS

Store all medicines out of reach of children

- Store at or below 30 °C.
- Store in the original package in order to protect from moisture.
- Do not remove the capsule from its blister until you are ready to take it. Do not use this medicine after the expiry date which is stated on the carton after EXP. 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).

6. Contents of the pack and other information

What GOMESIS contains

The active substance is aprepitant.

GOMESIS 80 mg capsules: Each capsule contains 80 mg aprepitant.

GOMESIS 125 mg capsules: Each capsule contains 125 mg aprepitant.

Contains sugar (sucrose)

Each 80 mg capsule contains 80 mg sucrose

Each 125mg capsule contains 125 mg sucrose

The other ingredients are:

Capsule content: Hydroxypropylcellulose (E463), microcrystalline cellulose sphere 500 (E460), sodium laurilsulfate, sucrose.

Capsule shell: Gelatin, Iron oxide red (E172), Titanium dioxide (E171).

What GOMESIS looks like and contents of the pack

GOMESIS 80 mg: Opaque, size 2 hard gelatin capsules with a white body and cap, containing white to off-white pellets.

GOMESIS 125 mg: Opaque, size 1 hard gelatin capsules with a white body and pink cap, containing white to off-white pellets.

GOMESIS 80 mg and 125 mg capsules and combi pack (containing GOMESIS 80 mg and 125 mg capsules) are packed in Aluminium-OPA/Alu/PVC blister, which consist of an OPA/Alu/PVC forming foil consisting of aluminium layer coated with a polyamide (OPA) film on one side and polyvinyl chloride (PVC) film on the other with an aluminium sealing foil.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: +27860287835

This leaflet was last revised in

-

Registration numbers

GOMESIS 80 mg capsules: 53/5.7.2/0084

GOMESIS 125 mg capsules: 53/5.7.2/0085

GOMESIS combi pack capsules: 53/5.7.2/0086.