PROPOSED PATIENT INFORMATION LEAFLET
EMISTOP 4 & 8 mg

SCHEDULING STATUS

S4

EMISTOP 4 mg solution for injection

EMISTOP 8 mg solution for injection

Ondansetron

EMISTOP is sugar-free

Read all of this leaflet carefully before you start taking EMISTOP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- EMISTOP 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 EMISTOP is and what it is used for

EMISTOP contains the active substance ondansetron, which belongs to a group of medicines called anti-emetics.

EMISTOP injection is used to prevent and treat nausea and vomiting caused by chemotherapy or radiotherapy and for the prevention and treatment of nausea and vomiting after surgery.

2. What you need to know before you take EMISTOP

EMISTOP should not be administered to you:

- if you are hypersensitive (allergic) to ondansetron, or to any of the ingredients of EMISTOP (see section 6)
- if you are pregnant
- during the first 12 weeks of your pregnancy
- if you have congenital long QT syndrome, which is seen on an electrocardiogram (ECG), an electrical recording of the heart operated by your healthcare provider
- if you are taking medicine called apomorphine which is used for treatment of Parkinson's disease.

Warnings and precautions

Tell your doctor or healthcare provider before being given EMISTOP:

- if you or your child has liver problems, as it may take longer for EMISTOP to be excreted, in this case, your doctor will give you the correct dose for your condition
- if you have had abnormal levels of electrolytes such as magnesium or potassium in your body, this may have symptoms such as, muscle weakness that can result in paralysis, respiratory failure, low blood pressure, muscle twitching, cramping during exercise and convulsions. EMISTOP may prolong your QT interval, which is seen on an electrocardiogram (ECG) performed by your healthcare provider, due to abnormalities in your heart rhythm. Your healthcare provider will take special precautions when giving you EMISTOP
- if you have signs of intestinal obstruction (blockage) – you will need to be monitored as EMISTOP is known to delay the time it takes for ingested food to travel through the human gut
- if you have dysrhythmias or cardiac conduction disorders (heartbeat disorders) or are being treated with antidysrhythmic (for irregular heartbeat)
- if you, after administration of EMISTOP, suddenly feel chest pain or tightness of the chest,

shortness of breath, sweating and you have a rapid heartbeat

- if you are taking other serotonergic medicines (medicines that are used to treat altered mental status, involuntary nervous system
  and neuromuscular abnormalities) as they may affect your mental health
- if you had tonsil surgery, using EMISTOP to stop vomiting and nausea may cause invisible bleeding
- if you or your child have problems with the levels of salts in your blood, such as potassium, sodium and magnesium
- if you or your child are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- if you are within the first 12 weeks of pregnancy, as EMISTOP increases the risk of your baby developing oral cleft palate and/or lip (openings or splits in the upper lip, the roof of the mouth or both).

Other medicines and EMISTOP

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

The following medicines may interact with your EMISTOP injection:

- apomorphine (used to treat Parkinson's disease), when used together with EMISTOP, may lower your blood pressure, you may have symptoms such as dizziness or lightheadedness, fainting (syncope), blurred vision, nausea, fatigue, lack of
  concentration and may also result in loss of consciousness, this may also affect your heart rhythm
- phenytoin, carbamazepine (treatments for epilepsy) and rifampicin (an antibiotic for treatment of tuberculosis (TB)) because they are known to reduce the levels of EMISTOP in the blood
- tramadol (painkiller), as EMISTOP is known to reduce its effect on pain

- anthracyclines (medicines used for heart problems) such as doxorubicin, daunorubicin or trastuzumab, antibiotics such as erythromycin, antifungal medicines such as ketoconazole, antiarrhythmics (medicines that treat abnormal heart rate) such as amiodarone and beta blockers (medicines that slow heart rate) such as atenolol or timolol, may affect your heart rate, when used together with EMISTOP
- serotonergic medicines which are medicines that are used to treat altered mental status, involuntary nervous system and neuromuscular abnormalities, including SSRIs (selective serotonin reuptake inhibitors) and SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression, may cause serotonin syndrome when used with EMISTOP.
  Symptoms of serotonin syndrome may include high body
  temperature, agitation, increased reflexes, tremor, sweating, dilated pupils, and diarrhoea.

EMISTOP with food and drink

EMISTOP can be administered with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using EMISTOP.

Safety in pregnancy has not been established (see EMISTOP should not be administered to you).

Ondansetron, as in EMISTOP**,** passes into breast milk, therefore nursing mothers should not breastfeed their babies.

Driving and using machines:

EMISTOP is not expected to interfere with your ability to drive or use machines.
It is not always possible to predict to what extent EMISTOP may interfere with the daily activities of a patient. Patients should ensure that

they do not engage in the above activities until they are aware of the measure to which EMISTOP affects them.

EMISTOP contains sodium

This should be taken into consideration if you are on a strictly controlled salt diet.

3. How to take EMISTOP

EMISTOP injection is for intravenous (into a vein) and intramuscular (into the muscle) use.
You will not be expected to give yourself EMISTOP**.** It will be given to you by a person who is qualified to do so.

Your doctor will decide on the correct dose for you based on your condition.

To prevent nausea and vomiting from chemotherapy or radiotherapy

Adults

On the day of chemotherapy or radiotherapy the recommended adult dose is 8 mg given by an injection into your vein or muscle, just before your treatment, and another 8 mg twelve hours later.
The usual adult intravenous dose does not exceed 8 mg.

On the following days, if your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you or your child may be given more than the usual dose of EMISTOP. Your doctor will decide this.

Children and adolescents

The doctor will decide the dose based on the child's weight or size (body surface area). On the day of chemotherapy, the first dose is given by an injection into the vein, just before your child's treatment.

On the following days oral dosing can commence twelve hours after the last intravenous dose and may be continued for up to 5 days.

To prevent and treat nausea and vomiting after an operation

Adults:

The usual dose for adults is 4 mg given by an injection into your vein or an injection into your muscle. For prevention this will be given just before your operation.

Children:

Your doctor will decide on the dose to be given. The maximum dose is 4 mg given as a slow injection into the vein. For prevention this will be given just before your operation.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

Your doctor will tell you how long your treatment with EMISTOP will last. If you have the impression that the effect of EMISTOP is too strong or too weak, tell your doctor or pharmacist.

If you receive more EMISTOP than you should

Since a healthcare provider will administer EMISTOP, they will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take EMISTOP

Since a healthcare provider will administer EMISTOP, it is unlikely that the dose will be missed.

4. Possible side effects

Not all side effects reported for EMISTOP are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using EMISTOP, please consult your

healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to EMISTOP. 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:

- seizures (fits or convulsions)
- disturbance in heart rhythm, abnormally rapid heartbeat (tachycardia), uneven heartbeat, slow heartbeat
- if you suddenly feel pain in your neck, jaw, shoulder or chest or tightness of the chest, shortness of breath, sweating fast heartbeat and fatigue (myocardial ischaemia).

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:

- headache
- hot flushes
- constipation, diarrhoea, stomach pain or stomach cramps
- allergic reaction around the injection site, rash.

Less frequent side effects:

- movement disorders, dizziness
- blurred vision, poor vision or temporary loss of eyesight, which usually comes back within 20 minutes
- your eyes may become fixed upwards, involuntarily (oculogyric crisis)
- low blood pressure
- hiccups, spasm of the vocal cords
- changes to liver function test results.

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 online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of EMISTOP. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store EMISTOP

Store all medicines out of reach of children.

Your doctor or pharmacist knows how to store EMISTOP. For single use only. Discard any unused portion. Store at or below 30 °C, keep well closed. Do not refrigerate or freeze. Keep ampoules in the outer carton, in order to protect from light.

Do not use EMISTOP injection after the expiry date shown on the carton.

Only clear solutions, free from particles, should be used. Do not use if ampoule is damaged.

Do not use after the expiry date stated on the carton. 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 EMISTOP contains

The active substance is ondansetron.

EMISTOP 4 mg: Each 2 mL ampoule contains ondansetron hydrochloride dihydrate equivalent to 4 mg ondansetron (2 mg/mL).
EMISTOP 8 mg: Each 4 mL ampoule contains ondansetron hydrochloride dihydrate equivalent to 8 mg ondansetron (2 mg/mL).

The other ingredients are:
Citric acid monohydrate, sodium citrate, sodium chloride, water for injection.

What EMISTOP looks like and contents of the pack

EMISTOP 4 mg is a clear and colourless solution, free from visible particles.

EMISTOP 8 mg is a clear and colourless solution, free from visible particles.

EMISTOP 4 mg is packed into a 2 mL clear and colourless type I glass ampoule with a blue dot. Each ampoule contains 2 mL solution for injection. 5 ampoules are packed into an outer carton.

EMISTOP 8 mg is packed into a 5 mL clear and colourless type I glass ampoule with a blue dot. Each ampoule contains 4 mL solution for injection. 5 ampoules are packed into an outer carton.

Holder of Certificate of Registration

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This leaflet was last revised in

23 November 2022

Registration date: 31 July 2014

Registration number

EMISTOP 4 mg: A45/5.10/0386

EMISTOP 8 mg: A45/5.10/0387

All strengths are not necessarily marketed.

NAMIBIA

EMISTOP 4 mg: NS2 15/5.10/0178

EMISTOP 8 mg: NS2 15/5.10/0179

ZAMBIA

EMISTOP 4 mg: POM 051/016

EMISTOP 8 mg: POM 051/017