PATIENT INFORMATION LEAFLET
EMISTOP RANGE

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

EMISTOP 4 mg (solution for injection)

EMISTOP 8 mg (solution for injection)

Read all of this leaflet carefully before EMISTOP is administered to you.

Keep this leaflet. You may need to read it again.

If you have any questions, please ask your doctor or pharmacist.

EMISTOP has been prescribed for you and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

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

2. WHAT EMISTOP IS USED FOR:

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.

3. BEFORE YOU RECEIVE EMISTOP:

You should not receive EMISTOP if:

- You are allergic to ondansetron or any of the ingredients.
- If you have congenital long QT syndrome.
- **EMISTOP** contains sodium. If you are on a sodium-controlled diet, speak to your doctor before been given this medicine.

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Take special care with EMISTOP injection if:

- **You have signs of intestinal obstruction (blockage) – you will need to be monitored.**
- **You have dysrhythmias or cardiac conduction disorders (heartbeat disorders) or are being treated with antidysrhythmic (for irregular heartbeat).**

Pregnancy and breast-feeding:

Pregnancy:

Please tell your doctor if you are pregnant or planning to be pregnant.

Breast-feeding:

Ondansetron passes into breast milk, therefore nursing mothers should not breast-feed.

If you are pregnant or breast-feeding your baby consult your doctor, pharmacist or other healthcare professional before using EMISTOP.

Driving and using machines:

EMISTOP has no effect on your ability to drive or use machines.

Taking other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **EMISTOP** with these medicines may cause undesirable interactions. Please consult your healthcare professional for advice.

The following medicines may interact with your EMISTOP injection:

- Phenytoin, carbamazepine (treatments for epilepsy).
- Rifampicin (an antibiotic for treatment of tuberculosis (TB)).
- Tramadol (painkiller).
- Beta-blockers (medicines that slow heart rate).
- Apomorphine (used to treat Parkinson's disease).

4. HOW EMISTOP WILL BE ADMINISTERED:

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EMISTOP injection is for intravenous (into a vein) and intramuscular (into the muscle) use and will be given to you by a nurse or a doctor.

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

If you receive more EMISTOP than you should:

Since your doctor or a nurse will administer **EMISTOP**, he/she will control the dosage.

However, in the event of overdosage your doctor will treat the side effects symptomatically.

5. POSSIBLE SIDE EFFECTS:

EMISTOP can have side effects. Serious allergic reactions may occur. Should your general health worsen while receiving **EMISTOP**, please consult your doctor, pharmacist or other health care professional for advice.

Treatment with EMISTOP should be stopped immediately, should any of the following side effects occur:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty breathing.
- Serious allergic reactions including skin reactions, fever, low blood pressure (dizziness), allergic pneumonitis (cough or other lung symptoms), shock (cold, clammy skin, irregular breathing, weakness, anxiety).
- Yellowing of the skin and eyes, also called jaundice.

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.

Frequent:

Constipation, sensation of warmth or flushing, headache.

Less frequent:

Allergic reaction around the injection site, rash, itching, hiccups.

Movement disorders, dizziness, heartbeat disturbances, low blood pressure, slow heartbeat,

blurred vision, severe allergic reaction.

Temporary changes in heartbeat.

Not all side effects reported for **EMISTOP** are included in this leaflet. If you notice any side effect not listed, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF EMISTOP:

Your doctor or pharmacist knows how to store **EMISTOP**. Store at or below 30 °C in a dry place. 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. Medicines should not be disposed of via wastewater or household waste. Return the expired medicine to you pharmacist for safe disposal.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.