AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS:

S4

Alepet 8 mg (solution for injection)

Alepet 4 mg (solution for injection)

Ondansetron hydrochloride dihydrate

Contains sodium: 1 ml solution for injection or infusion contains 3,6 mg of sodium as sodium citrate, sodium chloride and sodium hydroxide.

Read all of this leaflet carefully before you are given ALEPET

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

What is in this leaflet

1. What ALEPET is and what it is used for
2. What you need to know before you are given ALEPET
3. How ALEPET will be administered to you
4. Possible side effects
5. How ALEPET is stored
6. Contents of the pack and other information

1. WHAT ALEPET IS AND WHAT IT IS USED FOR

Alepet belongs to a group of medicines called anti-emetic medicines, medicines which help prevent you from feeling sick or being sick (nausea). Some medical treatment with medicines for treatment of cancer (chemotherapy) or radiotherapy can make you feel sick or be sick. Also after surgical treatment you can feel sick or be sick. Alepet may help to reduce these effects.

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2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ALEPET

YOU SHOULD NOT RECEIVE ALEPET IF:

- if you are allergic (hypersensitive) to ondansetron, any of the other ingredients of Alepet (see section 6), or to medicines from the same class (e.g. granisetron or dolasetron).
- if you experience nausea and vomiting after surgery while you are pregnant
- in the first 12 weeks of pregnancy, as it may be harmful to your baby. There is an increased risk of the baby developing a defect of the palate or lip.
- if you are taking a medicine called apomorphine for treatment of Parkinson's disease.
- if you have a heart rhythm disorder.

WARNINGS AND PRECAUTIONS

TAKE SPECIAL CARE WITH ALEPET:

- if you are hypersensitive to other medicines which help prevent feeling sick or being sick.
- if you have a blockage in your gut or suffer from severe constipation. Alepet can enhance the blockage or constipation.
- if you have cardiac problems or heart rhythm disorders. Alepet can make these conditions worse.
- if you experience chest pain or pressure (angina), shortness of breath, and other symptoms like sweating, nausea, or irregular heartbeats immediately after receiving Alepet.
- if you are on anti-depressants while receiving Alepet, as you may experience a serious reaction called serotonin syndrome (you may experience agitation, restlessness, confusion, and rapid heart rate).
- if you are having surgery to remove tonsils or adenoids, your doctor will monitor you for signs of bleeding.
- if your liver is not working as well as it should.

Children and adolescents

Alepet should not be used in children under 2 years of age, because insufficient experience is available.

OTHER MEDICINES AND ALEPET

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

Tell your doctor if you are taking any of the following:

- Medicines that may cause irregular heart rhythm and other cardiac side effects:
    - Antibiotics like doxorubicin or daunorubicin which are used in the treatment of cancer
    - Erythromycin (an antibiotic)
    - Antifungal medicines such as ketoconazole
    - Amiodarone (used to correct heart rhythm)
    - Atenolol, timolol (medicines used to treat high blood pressure.
- Anti-depressants such as fluoxetine which cause side effects when given together with Alepet
- Medicines that decrease the blood levels of Alepet:
    - Medicines for treating epilepsy (phenytoin, carbamazepine)
    - Rifampicin (used to treat tuberculosis)
- Tramadol (a strong pain killer) – Alepet may reduce the effect of tramadol.

PREGNANCY AND BREAST FEEDING:

- 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 healthcare professional for advice before receiving Alepet.
- Alepet should not be used during the first 12 weeks of pregnancy.
- It should not be used to treat nausea and vomiting if you are pregnant and have had surgery.
- Alepet passes into mother’s milk. Therefore, mothers receiving Alepet should NOT breast-feed.
- Ask your doctor or pharmacist for advice before taking Alepet.

DRIVING AND USING MACHINES

Alepet can cause seizures, dizziness and changes to your vision, which may affect your ability to drive or use machines.

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

Alepet contains sodium, this should be taken into consideration by patients on a sodium restricted diet.

3. HOW ALEPET WILL BE ADMINISTERED TO YOU

- Your health-care professional will administer Alepet.
- The usual dose will be calculated by your health-care professional according to the condition you suffer from.
- Alepet will be given to you as an infusion into your vein or an injection into your muscle.
- Your dose will be adjusted based on your age and if you have any other conditions, e.g. liver or kidney problems.
- Your doctor will tell you how long your treatment will last.
- If you have the impression that the effect of Alepet is too strong or too weak, tell your doctor.

IF YOU ARE GIVEN MORE ALEPET THAN YOU SHOULD:

Since a doctor will administer Alepet, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdose.

The following effects can occur after overdose: visual disturbances, severe constipation, low blood pressure and unconsciousness. There is no specific antidote to Alepet; for that reason, if overdose is suspected, only the symptoms should be treated. Tell your doctor if any of these symptoms occur. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Alepet can cause side effects.

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

Allergic reactions

If you have an allergic reaction, tell your doctor or a member of the medical staff straight away. You may need urgent medical treatment. The signs may include:

- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- collapse

Tell your doctor if notice any of the following:

Frequent side effects:

- headache
- a feeling of warmth or flushing
- constipation
- changes to liver function test results
- irritation and redness at the site of injection

Less frequent side effects:

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat or changes in your heart rhythm
- chest pain, shortness of breath, sweating, nausea
- fits
- unusual body movements or shaking
- feeling dizzy or light headed
- blurred vision
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of **ALEPET.**

5. HOW ALEPET IS STORED

Store at or below 25 ^{o}C.

Keep the ampoules in the carton until required for use.

Protect from light.

Keep out of reach of children.

Store in original package.

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

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Alepet is usually prepared at the time of administering the dose. However, once it has been diluted it is stable for 7 days at room temperature (below 25 °C) or in a refrigerator (between 2-8 °C).

6. CONTENT OF THE PACK AND OTHER INFORMATION

What ALEPET contains:

- The active substance is ondansetron.
- The other ingredients are sodium chloride, sodium citrate, citric acid monohydrate, sodium hydroxide and hydrochloric acid.

What ALEPET looks like and contents of the pack:

Alepet 4 mg injection: A clear colourless solution free from visible particles.

Alepet 8 mg injection: A clear colourless solution free from visible particles.

Alepet is packed as follows:

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Alepet 4: A 2 ml type I clear colourless glass ampoule with a red band and a red OPC dot, filled with 2 ml of solution, 5 ampoules per unit carton.

Alepet 8: A 5 ml type I clear colourless glass ampoule with a red band and a red OPC dot, filled with 4 ml of solution, 5 ampoules per unit carton.

HOLDER OF THE CERTIFICATE OF REGISTRATION:

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REGISTRATION NUMBER

ALEPET 4 : 42/5.10/0891

ALEPET 8 : 42/5.10/0892