Applicant	: Biomab Innovation (Pty) Ltd
Proprietary name	: Onicit
Dosage form and strength	: Solution for Injection, 250 mcg / 5 ml
Date of submission	: 23 May 2023

PATIENT INFORMATION LEAFLET FOR ONICIT

SCHEDULING STATUS: S4

ONICIT Solution for injection

Palonosetron (as hydrochloride)

Contains sugar

Each 1 mL of ONICIT contains 41,5 mg mannitol

Read all of this leaflet carefully before you are given ONICIT

- 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.
- ONICIT 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 ONICIT is and what it is used for
2. What you need to know before you are given ONICIT
3. How to receive ONICIT
4. Possible side effects
5. How to store ONICIT
6. Contents of the pack and other information

1. What ONICIT is and what it is used for

ONICIT is used for the prevention of nausea and vomiting associated with cancer chemotherapy.

2. What you need to know before you are given ONICIT

You should not be given ONICIT:

- if you are hypersensitive (allergic) to palonosetron or to any of the other ingredients of ONICIT (listed in section 6).
- if you have heart problems including a problem called “congenital long QT syndrome”
- if you are taking any medicines that may affect your heart rhythm (prolong the QT interval)
- if you have liver failure
- if you are taking apomorphine (a medicine used to treat Parkinson’s disease)

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have acute bowel obstruction or a history of repeated constipation
- if you are taking ONICIT in addition to other medicines that may induce an abnormal heart rhythm
- if you have low potassium in your blood
- if you have low magnesium in your blood
- if you are taking any medicines to treat anxiety or depression

It is not recommended that you receive ONICIT in the days following chemotherapy unless you are receiving another chemotherapy cycle.

Other medicines and ONICIT

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

Tell your doctor if you are taking:

- Anthracyclines (such as doxorubicin, daunorubicin) which are used to treat various cancers
- Trastuzumab which is used to treat breast cancer
- Erythromycin which is used to treat infections
- Ketoconazole which is used to treat fungal infections
- Amiodarone which is used to treat and prevent irregular heartbeats
- Atenolol or timolol which are used to reduce your blood pressure

Pregnancy and breastfeeding

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

ONICIT should not be used in pregnancy and breastfeeding should be discontinued during therapy.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Since ONICIT may induce dizziness, somnolence (sleepiness) or fatigue, take care when driving or operating machines.

It is not always possible to predict to what extent ONICIT 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 ONICIT affects them.

3. How to receive ONICIT

You will not be expected to give yourself ONICIT. It will be given to you by a person who is qualified to do so.

A doctor or nurse will normally inject ONICIT about 30 minutes before the start of chemotherapy.

You should not receive another dose of ONICIT within 7 days after receiving the last dose.

Use in patients under 18 years of age is not recommended.

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

If you receive more ONICIT than you should

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive ONICIT

Since a health care provider will administer ONICIT, it is unlikely that the dose will be missed.

4. Possible side effects

ONICIT can have side effects.

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

Tell your doctor or nurse right away if you have any of the following symptoms of a serious allergic reaction: swelling of the lips, face, tongue or throat, difficulty in breathing or itchy lumpy rash (hives).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- dizziness
- constipation
- diarrhoea

Less frequent side effects

- abnormally high or low levels of potassium in the blood
- low levels of calcium in the blood
- decrease or loss of appetite
- high levels of sugar in the blood or sugar in the urine
- elevated moods or feelings of anxiousness
- sleepiness or trouble sleeping
- numbness, burning, prickling or tingling sensations on the skin
- impaired vision or eye irritation
- motion sickness
- ringing in the ear
- high, low or abnormal heart rate
- reduced blood flow in the blood vessels of the heart
- electrocardiogram abnormalities (QT prolongation)
- high or low blood pressure
- change in the colour of the vein and/or veins becoming larger

- hiccups
- indigestion, abdominal (stomach) pain, dry mouth, flatulence
- high levels of the pigment bilirubin in the blood
- itchy skin rash
- joint pain
- difficulty urinating
- weakness, tiredness, fever or flu like symptoms
- high levels of certain liver enzymes
- burning or pain at the site of injection

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, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions 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 ONICIT.

5. How to store ONICIT

- Store all medicines out of reach of children.
- Store at or below 25 °C. Do not refrigerate.
- Protect from light.
- Store vial in carton until required for use.
- Do not use after the expiry date stated on the label.
- Single use only, any unused solution should be discarded.

6. Contents of the pack and other information

What ONICIT contains

The active substance is palonosetron (as palonosetron hydrochloride). Each 1 mL solution contains 50 micrograms palonosetron (as palonosetron hydrochloride). Each vial of 5 mL solution contains 250 micrograms palonosetron (as palonosetron hydrochloride). ONICIT solution is an isotonic solution for injection.

The other ingredients are mannitol, disodium edetate, sodium citrate, citric acid monohydrate, water for injection, sodium hydroxide solution and hydrochloric acid solution.

What ONICIT looks like and contents of the pack

ONICIT is a clear, essentially colourless solution free from evidence of contamination.

ONICIT is supplied in a pack of one glass vial, which contains 5 mL of the solution. Each vial contains one dose.

Holder of Certificate of Registration

Biomab Innovation (Pty) Ltd

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Woodmead, 2144

Biomab Innovation (Pty) Ltd

This leaflet was last revised in

18 September 2023

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