PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking ONICIT.

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

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

This medicine 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.

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM:

ONICIT (solution for injection)

Palonosetron (as hydrochloride)

WHAT ONICIT CONTAINS:

The active substance is palonosetron (as hydrochloride). Each one ml solution contains 50 micrograms palonosetron. Each vial of 5 ml solution contains 250 micrograms palonosetron. 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 IS USED FOR:

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

ONICIT can be used by patients 18 years and older.

BEFORE YOU TAKE ONICIT

Do not take ONICIT:

If you are hypersensitive (allergic) to palonosetron or any of the other ingredients of ONICIT.

Take special care with ONICIT:

If you have acute bowel obstruction or a history of repeated constipation.
Also if you are taking ONICIT in addition to other medicines that may induce an abnormal heart rhythm.
If you have heart problems including a problem called “congenital QT syndrome”
If you have low potassium in your blood.
If you have low magnesium in your blood.

Pregnancy

If you are pregnant or think you might be pregnant, ask your doctor, pharmacist or other healthcare professional for advice before using ONICIT.

Breast-feeding

If you are breast-feeding your baby, ask your doctor, pharmacist or other healthcare professional for advice before using ONICIT.

Driving and using machines:

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

Taking other medicines:

Please inform your doctor, pharmacist or other healthcare professional if you are taking or have recently taken any other medicines, including complementary or traditional medicines.

Especially tell your doctor if you are taking:

- “water pills” (diuretics)
- medicine to control your heartbeat (anti-arrhythmics)
- anthracycline (an anti-cancer medicine)

HOW TO USE ONICIT

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

The usual dose of ONICIT is 250 micrograms given as a rapid injection (bolus injection) into a vein.

ONICIT is for a single use. Any unused solution should be discarded.

Repeated dosing of ONICIT within a seven day interval is not recommended.

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

In the event of over dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

ONICIT can have side effects.

The most common side effects (those likely to affect between 1 and 10 patients in every 100) are the following: headache, dizziness, constipation and diarrhoea.

Other uncommon side effects (those likely to affect between 1 and 10 patients in every

1 000) are: appetite decreased and loss of appetite, anxiety, euphoria (sense of wellbeing), insomnia (inability to sleep), somnolence (sleepiness), excessive sleep, paresthesia (abnormal sensation as burning, prickling, formication, etc.), peripheral sensory neuropathy, vision impairment, motion sickness, ringing in the ear, rapid or slow heartbeat, premature heartbeat, heart rate variation, blood pressure high or low, vein discolouration or distended, hiccups, flatulence, dry mouth, impaired digestion, abdominal pain and upper abdominal pain, allergic dermatitis (allergic inflammation of the skin), pruritic rash, joint pain, urinary retention, feeling hot, influenza like illness, weakness, fatigue, eye irritation, fever, disorders of metabolism, low or high calcium levels in the blood, blood potassium decreased, high sugar levels in the blood, high bilirubin levels in the blood, sugar in the urine, increased liver enzymes (transaminases), heart ischemia, electrocardiogram abnormalities (QT prolonged).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ONICIT:

Keep all medicines out of the reach and sight 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.

PRESENTATION OF ONICIT

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

IDENTIFICATION OF ONICIT

ONICIT is a colourless solution for injection into a vein.

REGISTRATION NUMBER

A40/5.10/0322

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pfizer Laboratories (Pty) Ltd

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