

Patient Information Leaflet
Information for the Patient about
ONDANSETRON CIPLA TABLETS 4 / 8

Read this entire leaflet carefully before you start taking ONDANSETRON CIPLA.

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

S4

PROPRIETARY NAME AND DOSAGE FORM

ONDANSETRON CIPLA TABLETS 4 (Tablets)

ONDANSETRON CIPLA TABLETS 8 (Tablets)

WHAT ONDANSETRON CIPLA CONTAINS

The active ingredient in **ONDANSETRON CIPLA** is ondansetron.

ONDANSETRON CIPLA TABLETS 4 : Each tablet contains ondansetron
4 mg (as hydrochloride dihydrate).

ONDANSETRON CIPLA TABLETS 8 : Each tablet contains ondansetron
8 mg (as hydrochloride dihydrate).

Inactive ingredients include lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, and Opadry Y-1-7000 white (hydroxypropyl cellulose, titanium dioxide, macrogol (PEG 400)).

Contains sugar: Lactose monohydrate

ONDANSETRON CIPLA TABLETS 4: 46,00 mg.

ONDANSETRON CIPLA TABLETS 8: 92,00 mg.

WHAT ONDANSETRON CIPLA IS USED FOR

ONDANSETRON CIPLA tablets are used to treat nausea and vomiting caused by chemotherapy (medicines for the treatment of cancer) or radiotherapy (radiation therapy).

ONDANSETRON CIPLA is also used to prevent and treat nausea and vomiting postoperatively (after surgery).

BEFORE YOU TAKE ONDANSETRON CIPLA

Do NOT take ONDANSETRON CIPLA if you:

- Are hypersensitive or allergic to ondansetron or any of the ingredients in the preparation.
- Are pregnant (see "**Pregnancy and breastfeeding**").
- Are taking apomorphine (used to treat Parkinson's disease).
- Have been diagnosed with an inborn heart condition known as long QT syndrome.

- Have been prescribed ondansetron during the first 12 weeks of pregnancy, irrespective of your indication.

Take special care with ONDANSETRON CIPLA

Please inform your doctor if you have been diagnosed with liver disease or impaired liver function. You may require a lower dose of **ONDANSETRON CIPLA**. Your total daily dose should not be more than 8 mg.

Please inform your doctor if you have previously been told that you have an abnormal electrocardiogram (ECG), you have previously been diagnosed with an abnormal heart rate or rhythm, or you are taking other medicines that may affect your heart rate or rhythm.

Your doctor may perform blood tests before you start treatment with **ONDANSETRON CIPLA** to rule out low blood potassium levels and low blood magnesium levels. Your doctor will treat these electrolyte abnormalities before you start treatment with **ONDANSETRON CIPLA**.

Please inform your doctor if you have previously been diagnosed with hypersensitivity (allergy) to medicines that act on serotonin receptors. If you experience swelling of the face, lips, or tongue, difficult breathing, shortness of breath, nausea, and skin rash or itching, please report to your doctor immediately, because you may be allergic to **ONDANSETRON CIPLA**.

ONDANSETRON CIPLA may reduce the motility of your colon (large bowel), thus causing stool and fluids to pass more slowly through it. You may develop constipation. Please inform your doctor as soon as possible if you develop stomach discomfort and bloating, loss of appetite, and/or vomiting.

ONDANSETRON CIPLA may increase the risk of your unborn baby developing oral cleft palate and or lip during the first 12 weeks of pregnancy.

Pregnancy and breastfeeding

Do not take **ONDANSETRON CIPLA** if you are pregnant (see "**Do NOT take ONDANSETRON CIPLA**") or breastfeeding your baby.

If you are pregnant or breastfeeding your baby while taking ONDANSETRON CIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

It is unlikely that **ONDANSETRON CIPLA** will impair your ability to drive or operate machinery.

Important information about some of the ingredients in ONDANSETRON CIPLA:

ONDANSETRON CIPLA contains lactose. If you are lactose intolerant, please speak to your doctor or pharmacist before taking **ONDANSETRON CIPLA**, as you may experience unwanted side-effects, such as nausea, cramping, bloating, diarrhoea, and flatulence. If you suffer from a condition known as hereditary galactose intolerance,

you should not take **ONDANSETRON CIPLA**. You should also not take **ONDANSETRON CIPLA** if you suffer from the rare Lapp lactase deficiency. Please discuss this with your treating doctor if you are unsure.

Taking other medicines with ONDANSETRON CIPLA

Please inform your doctor or pharmacist if you are taking any other medicines that may influence your heart rate or rhythm, and/or cause electrolyte imbalance, such as diuretics (water tablets) (see "**Take special care with ONDANSETRON CIPLA**"), because this may lead to a dangerous interaction if combined with **ONDANSETRON CIPLA**.

If you are taking any of the following medicines, please discuss the use of **ONDANSETRON CIPLA** with your doctor, as you may require special precautions:

- Apomorphine, for the treatment of Parkinson's disease, as severe low blood pressure, loss of consciousness or abnormal heart rhythms may occur (see "**Do NOT take ONDANSETRON CIPLA if you**").
- Phenytoin or carbamazepine (for treatment of epilepsy) and rifampicin (for treatment of tuberculosis), as these medicines may decrease the effect of **ONDANSETRON CIPLA**.
- Tramadol, for treatment of pain, as **ONDANSETRON CIPLA** may reduce the pain-relieving effect of tramadol.

<p>If you are taking other medicines on a regular basis, including complementary or traditional medicines, concomitant use of these medicines with</p>

ONDANSETRON CIPLA may cause undesirable interactions. Please consult your doctor or pharmacist, or other healthcare professional for advice.

HOW TO TAKE ONDANSETRON CIPLA

Always take **ONDANSETRON CIPLA** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with others.

For the treatment of nausea and vomiting induced by chemotherapy or radiotherapy, the adult dose is one **ONDANSETRON CIPLA TABLETS 8** tablet (8 mg) or two **ONDANSETRON CIPLA TABLETS 4** tablets 1 to 2 hours before treatment, followed by **ONDANSETRON CIPLA TABLETS 8** every twelve hours (twice daily). If delayed or prolonged vomiting is expected, your doctor may prescribe **ONDANSETRON CIPLA** for a period of up to 5 days after a course of chemotherapy or radiotherapy.

In children, **ONDANSETRON CIPLA** is usually administered orally after chemotherapy at a dose of one **ONDANSETRON CIPLA TABLETS 4** tablet (4 mg) every 12 hours, for up to 5 days.

For the prevention of nausea and vomiting following surgery, the usual dose in adults is 16 mg (two **ONDANSETRON CIPLA TABLETS 8** tablets) one hour before the start of anaesthesia.

The safety and efficacy of **ONDANSETRON CIPLA** for the prevention of nausea and vomiting following surgery in elderly patients have not been established.

If you have the impression that the effect of **ONDANSETRON CIPLA** is too strong or too weak, please speak to your doctor or pharmacist.

If you take more ONDANSETRON CIPLA than you should

In the event of an overdose, or if someone else has taken your medicine by mistake, you, or this other person, may experience constipation, visual disturbances, low blood pressure or fainting spells. **In the event of an overdose, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.**

If you forget to take ONDANSETRON CIPLA

Always take **ONDANSETRON CIPLA** as prescribed. If you miss a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS

ONDANSETRON CIPLA may have side-effects.

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

Serious side-effects (which occur less frequently) that you should report to your doctor as a matter of urgency include:

- Hypersensitivity or allergic reactions presenting with swelling of the face, lips, or tongue, shortness of breath or tightness of the chest, skin rash or itching (see **"Take special care with ONDANSETRON CIPLA"**)
- Seizures or convulsions
- Extreme restlessness, abnormal or involuntary muscle movements including abnormal eye movements, severe muscle spasms, and/or tremors

Other side-effects (which occur less frequently) that you should report to your doctor as soon as possible include:

- Palpitations or abnormal heart rate or rhythm

Please report any of the following side-effects to your doctor or pharmacist or other healthcare professional if they continue or become bothersome:

- Those that occur frequently:
 - Headache
 - Sensation of warmth or flushing
 - Constipation (see **"Take special care with ONDANSETRON CIPLA"**)
- Those that occur less frequently:
 - Dizziness after standing up (due to low blood pressure)
 - Hiccups

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

STORAGE AND DISPOSING OF ONDANSETRON CIPLA

Store at or below 25 °C.

Keep the blisters in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF ONDANSETRON CIPLA:

ONDANSETRON CIPLA TABLETS 4 : Cartons of 10, 15 or 100 tablets, blister-packed in transparent PVC/PVDC aluminium foil blister strips.

ONDANSETRON CIPLA TABLETS 8: Cartons of 10, 15 or 100 tablets, blister-packed in transparent PVC/PVDC aluminium foil blister strips.

IDENTIFICATION OF ONDANSETRON CIPLA:

ONDANSETRON CIPLA TABLETS 4: White, circular, biconvex, film-coated tablet, marked "4" on one side and plain on the other side.

ONDANSETRON CIPLA TABLETS 8: White, circular, biconvex, film-coated tablet, marked “8” on one side and a central breakline on the other side.

REGISTRATION NUMBERS

ONDANSETRON CIPLA TABLETS 4: A38/5.10/0435

ONDANSETRON CIPLA TABLETS 8: A38/5.10/0436

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF

REGISTRATION

CIPLA Medpro (PTY) LTD

Building 9, Parc du Cap

Mispel Street

Bellville

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