

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

**[HA596 trade name]<sup>†</sup>**

Ondansetron (as hydrochloride dihydrate)

*If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What [HA596 trade name] is and what it is used for
2. What you need to know before you take [HA596 trade name]
3. How to take [HA596 trade name]
4. Possible side effects
5. How to store [HA596 trade name]
6. Contents of the pack and other information

#### 1. What [HA596 trade name] is and what it is used for

[HA596 trade name] contains ondansetron, which helps to stop you feeling sick (nausea) or being sick (vomiting).

[HA596 trade name] can be used in patients with HIV for:

- managing nausea and vomiting caused by chemotherapy (cancer treatment) in adults and in teenagers and children over 6 months of age
- managing nausea and vomiting caused by radiotherapy in adults
- preventing nausea and vomiting that can occur after surgery in adults

#### 2. What you need to know before you take [HA596 trade name]

##### Do not take [HA596 trade name]

- if you are allergic to ondansetron or any other ingredient of this medicine (listed in section 6).
- if you are taking apomorphine (a medicine for Parkinson's disease that is given by injection)

##### Warnings and precautions

Talk to your health care provider before taking [HA596 trade name] if you:

- have a blockage in your gut or suffer from severe constipation
- are due to have surgery to the adenoids or tonsils
- have a heart problem (e.g. heart failure which causes shortness of breath and swollen ankles).
- have uneven heartbeat (arrhythmia)
- have liver problems

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- have had blood tests that show abnormal levels of substances such as potassium, sodium and magnesium.

If any of the above apply, tell your health care provider before starting [HA596 trade name].

### **Other medicines and [HA596 trade name]**

[HA596 trade name] may have an effect on other medicines and other medicines may have an effect on [HA596 trade name].

Tell your health care provider if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your health care provider if you are taking any of the following medicines:

- SSRIs (selective serotonin reuptake inhibitors) used to treat depression including citalopram, escitalopram fluoxetine, fluvoxamine, paroxetine, sertraline
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression including duloxetine, venlafaxine
- certain cancer medicines (especially trastuzumab, and anthracyclines such as doxorubicin, daunorubicin)
- beta-blockers such as atenolol and timolol (medicines to treat high blood pressure, certain heart conditions or anxiety, or to prevent migraine, or as eye drops to treat eye problems)
- medicines to treat epilepsy (carbamazepine, phenytoin)
- antibiotics (such as erythromycin, rifampicin)
- medicines to treat heart problems such as abnormal heartbeats (such as amiodarone)
- medicines to treat fungal infections such as itraconazole
- methadone, a medicine to treat opioid dependence
- haloperidol, a medicine to treat mental illness such as schizophrenia
- tramadol (a medicine to treat pain)

### **Pregnancy and breast-feeding**

#### *Pregnancy*

Before you start treatment with [HA596 trade name], tell your health care provider if you are pregnant or think you might be pregnant or if you are planning to have a baby.

You should not use [HA596 trade name] during the first 3 months of your pregnancy. Your health care provider may advise you to use effective contraception during treatment with [HA596 trade name].

#### *Breast-feeding*

You should not breast-feed your infant whilst taking [HA596 trade name]. Ask your health care provider for advice before taking any medicine.

### **Driving and using machines**

[HA596 trade name] is not likely to affect your ability to drive or operate machinery. However, make sure you feel well enough to take on any skilled tasks.

#### *Excipients*

Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

This medicine may contain traces of cow's milk proteins. If you are allergic to cow's milk, talk to your health care provider before taking this medicine.

### **3. How to take [HA596 trade name]**

Always take [HA596 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

### ***To prevent nausea and vomiting from chemotherapy or radiotherapy***

#### ***Adults***

The usual dose of [HA596 trade name] is 1 tablet 1 to 2 hours before your chemotherapy or radiotherapy. For some types of chemotherapy your health care provider may ask you to take up to 3 tablets before chemotherapy. Your health care provider may ask you to take 1 more tablet after 12 hours and continue taking 1 tablet twice daily for up to 5 days.

#### ***Children aged over 6 months and teenagers up to 17 years***

In children, the health care provider will work out the dose based on the child's size (body surface area).

The usual dose of [HA596 trade name] for a child with a body surface area larger than 1.2 m<sup>2</sup> is 1 tablet twice daily for up to 5 days. For children who cannot swallow the tablet, other products that can provide a lower dose of the active substance in this medicine may be used.

### ***To prevent nausea and vomiting after an operation***

#### ***Adults***

The usual dose of [HA596 trade name] is 2 tablets 1 hour before your operation

#### ***Children aged over 1 month and teenagers up to 17 years***

In children and teenagers this medicine is usually given by injection for preventing nausea and vomiting after an operation.

#### ***If you vomit after taking [HA596 trade name]***

If you vomit within 1 hour of taking [HA596 trade name], then take the same dose again.

If you vomit more than an hour after taking the dose, then you do not need to take an extra dose and you can take the next dose as usual when it is due.

If you continue to feel sick, tell your health care provider.

#### ***If you take more [HA596 trade name] than you should***

If you take too many tablets of [HA596 trade name], you may have effects such as problems with vision, low blood pressure (which could cause dizziness or faintness) or irregular heartbeat.

If you or your child take more [HA596 trade name] than you should, talk to a health care provider for advice. If possible, show them the [HA596 trade name] pack.

#### ***If you forget to take [HA596 trade name]***

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

#### ***If you stop taking [HA596 trade name]***

Do not stop taking [HA596 trade name], even if you are feeling well, without checking with a health care provider.

If you have any questions on the use of this medicine, ask your health care provider

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, but not everybody gets them.

Some side effects could be serious. If you get any of the following, tell your health care provider immediately:

- *Allergic reactions*, a rare side effect, which can cause
  - 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
- *Heart attack (myocardial ischemia)*, which can cause
  - sudden chest pain or chest tightness

***Other side effects include***

*Very common side effects (may affect more than 1 in 10 people)*

- headache

*Common (may affect up to 1 in 10 people)*

- a feeling of warmth or flushing
- constipation

*Uncommon (may affect up to 1 in 100 people)*

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heartbeat
- slow heartbeat
- chest pain
- fits
- unusual body movements or shaking
- blood tests showing changes to how your liver is working

*Rare (may affect up to 1 in 1,000 people)*

- feeling dizzy or lightheaded
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

*Very rare (may affect up to 1 in 10,000 people)*

- poor vision or temporary loss of eyesight, which usually gets better within 20 minutes

**Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

**5. How to store [HA596 trade name]**

Do not store above 30°C. Protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What [HA596 trade name] contains**

- The active ingredient is ondansetron
- The other ingredients of [HA596 trade name] are:

*Core tablet:* lactose monohydrate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate

*Film coat:* titanium dioxide, hypromellose, triacetin, Iron Oxide Yellow

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

**What [HA596 trade name] looks like and contents of the pack**

[HA596 trade name] are yellow, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets are plain on both sides.

[HA596 trade name] are packed in aluminium foil on aluminium foil blister cards, containing 10 or 30 tablets. Available in packs of 1x10, 2x10, 3x10, 5x10, 6x10, 9x10, 10x10 and 30x10 tablets or 1x30, 2x30, 3x30 and 10x30 tablets.

**Supplier and Manufacturer**

***Supplier***

Cadila Pharmaceuticals Limited  
1389, Trasad Road  
Dholka Ahmedabad  
Gujarat 382 225  
India  
Tel: +91 2714-221481 / 221483 / 221484  
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***Manufacturer***

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1389, Trasad Road  
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Gujarat 382 225  
India  
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Fax: +91 2714 220315  
E-mail: [pharmacovigilance@cadilapharma.com](mailto:pharmacovigilance@cadilapharma.com)

For any information about this medicine, contact the supplier

**This leaflet was last revised in March 2025**

*Detailed information on this medicine is available on the World Health Organization (WHO) website:*  
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>