PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ONDANSETRON 4 ODF PHARMA-Q, orodispersible films

ONDANSETRON 8 ODF PHARMA-Q, orodispersible films

Ondansetron (as ondansetron hydrochloride dihydrate)

Contains sweetener (ONDANSETRON 4 ODF PHARMA-Q contains 4 mg and ONDANSETRON 8 ODF PHARMA-Q contains 8 mg sucralose)

Sugar free

Read all of this leaflet carefully before you take ONDANSETRON ODF PHARMA-Q:

- 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.
- ONDANSETRON ODF PHARMA-Q 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 ONDANSETRON ODF PHARMA-Q is and what it is used for

The active substance of ONDANSETRON ODF PHARMA-Q is ondansetron, which belongs to a group of medicines called anti-emetics.

ONDANSETRON ODF PHARMA-Q is indicated for the treatment of nausea and vomiting caused by cancer chemotherapy and radiotherapy.

ONDANSETRON ODF PHARMA-Q is also indicated for the prevention and treatment of nausea and vomiting after an operation.

2. What you need to know before you use ONDANSETRON ODF PHARMA-Q

Do not take ONDANSETRON ODF PHARMA-Q:

- If you are hypersensitive (allergic) to ondansetron or any of the other ingredients of ONDANSETRON ODF PHARMA-Q (listed in section 6).
- If you are taking apomorphine (used to treat Parkinson's disease).
- During the first 12 weeks of your pregnancy (see section 2 "Pregnancy and breastfeeding").
- To treat nausea and vomiting after having an operation while you are pregnant (see section 2 "Pregnancy and breastfeeding").
- If you have an inherited heart rhythm disorder (known as long QT syndrome).

Warnings and precautions:

Take special care with ONDANSETRON ODF PHARMA-Q:

- If you are hypersensitive to medicines similar to ondansetron, such as granisetron or palonosetron.
- If you have ever had heart problems.
- If you have heart rhythm problems.
- If you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- If you have a blockage in your gut, you should be monitored very carefully after using ONDANSETRON ODF PHARMA-Q.

- If you have just had or are going to have your adenoids (which are located at the back of the nasal cavity), or tonsils removed. The prevention of nausea and vomiting with ONDANSETRON ODF PHARMA-Q may hide bleeding that occurs in an area that is not visible.
- If you have liver problems, the total daily dose of 8 mg should not be exceeded.

Children and adolescents:

Paediatric patients receiving ondansetron, as in ONDANSETRON ODF PHARMA-Q with chemotherapeutic medicines that cause toxic effects of the liver, should be closely monitored for weakened liver function.

Other medicines and ONDANSETRON ODF PHARMA-Q:

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

Tell your doctor if you are using:

- Apomorphine (used for treating Parkinson's disease) as this medicine should not be taken together with ONDANSETRON ODF PHARMA-Q (see section 2, "Do not take ONDANSETRON ODF PHARMA-Q").
- Trastuzumab and anthracyclines including doxorubicin, daunorubicin (used for treatment of certain cancers).
- Erythromycin or ketoconazole (used to treat bacterial or fungal infections).
- Amiodarone (used to treat heart rhythm problems).
- Atenolol, timolol (used to treat certain heart or eye problems, anxiety or to prevent migraines).
- Selective serotonin reuptake inhibitors (SSRIs) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram (used to treat depression and/or anxiety).
- Serotonin noradrenaline reuptake inhibitors (SNRIs) including venlafaxine, duloxetine (used to treat depression and/or anxiety).

- Carbamazepine or phenytoin (used to treat epilepsy).
- Rifampicin (used to treat infections such as tuberculosis [TB]).
- Tramadol (used to treat pain).

Pregnancy and breastfeeding:

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 health care provider for advice before taking ONDANSETRON ODF PHARMA-Q.

If you are a woman of childbearing potential, you should consider the use of effective contraception while taking ONDANSETRON ODF PHARMA-Q, as well as for two days after stopping treatment with ONDANSETRON ODF PHARMA-Q.

Do not use ONDANSETRON ODF PHARMA-Q during the first 12 weeks of your pregnancy, as ONDANSETRON ODF PHARMA-Q can increase the risk of a baby being born with a cleft lip and/or a cleft palate (openings or splits in the upper lip and/or the roof of the mouth).

ONDANSETRON ODF PHARMA-Q should not be used during breastfeeding. This is because small amounts pass into the mother’s milk.

Driving and using machines:

ONDANSETRON ODF PHARMA-Q may cause symtoms such as headache, seizures (fits/convulsions) or blurry vision, that can affect your ability to drive a vehicle and use machines (see section 4.8).

It is not always possible to predict to what extent ONDANSETRON ODF PHARMA-Q 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 ONDANSETRON ODF PHARMA-Q affects you.

3. How to take ONDANSETRON ODF PHARMA-Q

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

Always take ONDANSETRON ODF PHARMA-Q exactly as your doctor has told you. Check with your doctor if you are not sure.

ONDANSETRON ODF PHARMA-Q is to be placed on the top of the tongue, where it will disperse within seconds, then swallow.

To prevent nausea and vomiting induced by cancer chemotherapy and radiotherapy:

The usual adult dose is 8 mg twice daily for 5 days. On the day of treatment, ONDANSETRON ODF PHARMA-Q can be taken one to two hours before treatment.

Your doctor will determine the dose for a child.

To prevent nausea and vomiting after an operation:

The usual adult dose is 16 mg taken one hour before your operation.

Your doctor will tell you how long your treatment with ONDANSETRON ODF PHARMA-Q will last.

If you have the impression that the effect of ONDANSETRON ODF PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you take more ONDANSETRON ODF PHARMA-Q than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining medicine with you so the doctor can see what you have taken.

If you forget to take ONDANSETRON ODF PHARMA-Q:

Do not take a double dose to make up for forgotten individual doses. Take the next dose as usual, when it is time to take it.

4. Possible side effects

ONDANSETRON ODF PHARMA-Q can have side effects.

Not all side effects reported for ONDANSETRON ODF PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ONDANSETRON ODF PHARMA-Q, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking ONDANSETRON ODF PHARMA-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ONDANSETRON ODF PHARMA-Q. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Seizures (convulsions or fits).
- Sudden chest pain or chest tightness.
- Uneven or slow heartbeat (dysrhythmia or bradycardia).
- Abnormal or disturbance in your heart rhythm (sometimes causing a sudden loss of consciousness).
- Painful, blistering or peeling skin rash, such as toxic epidermal necrolysis.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects that may occur frequently:

- Headache.
- A sensation of warmth or flushing.
- Constipation.

Side effects that may occur less frequently:

- Involuntary movements of muscles.
- Poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.
- Low blood pressure which can make you feel dizzy.
- Hiccups.
- Changes to liver function test results.

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ONDANSETRON ODF PHARMA-Q.

5. How to store ONDANSETRON ODF PHARMA-Q

- Store at or below 25 °C.
- Protect from direct sunlight.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ONDANSETRON ODF PHARMA-Q contains:

The active ingredient is ondansetron.

ONDANSETRON 4 ODF PHARMA-Q: Each orodispersible film contains 4 mg ondansetron (as ondansetron hydrochloride dihydrate).

ONDANSETRON 8 ODF PHARMA-Q: Each orodispersible film contains 8 mg ondansetron (as ondansetron hydrochloride dihydrate).

The other ingredients are banana flavour powder (spray dried 0473070), glycerine, hydroxypropyl methylcellulose (hypromellose Methocel E15 premium LV), polacrilin potassium (Kyron T-134), polysorbate 80, povidone and hypromellose solution, povidone (Kollidon 30), purified water, sucralose, titanium dioxide (1171.E171) and vanilla flavour powder (0473072).

What ONDANSETRON ODF PHARMA-Q looks like and contents of the pack

ONDANSETRON 4 ODF PHARMA-Q: White to off white opaque rectangular shape strip with matte finish on one side and other side is smooth.

ONDANSETRON 8 ODF PHARMA-Q: White to off white opaque rectangular shape strip with matte finish on one side and other side is smooth.

4-Ply laminated pouch containing 1 orodispersible film. The pouch material is composed of peelable LDPE, aluminium foil, polyethylene terephthalate (PET) and paper (opaque laminating base).

Pack size: 10 pouches are packed in an outer carton.

Holder of certificate of registration

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Access to the corresponding Professional Information

https://www.pharmaq.co.za