

APX-ONDANSETRON

Ondansetron (as hydrochloride dihydrate) 4 mg and 8 mg film-coated tablets

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use APX-ONDANSETRON.

This leaflet answers some common questions about APX-ONDANSETRON. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking APX-ONDANSETRON against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What APX-ONDANSETRON is used for

APX-ONDANSETRON contains a medicine called ondansetron. This belongs to a group of medicines called serotonin receptor-3 antagonists.

APX-ONDANSETRON is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.

APX-ONDANSETRON should only be used to treat the nausea and vomiting for which they have been prescribed.

Your doctor may have prescribed APX-ONDANSETRON for another reason. If you want more information, ask your doctor.

APX-ONDANSETRON is not addictive.

Before you take APX-ONDANSETRON

Do not take if:

You must not take APX-ONDANSETRON if:

- **you are taking apomorphine (used to treat Parkinson's disease);**
- **you have ever had an allergic reaction to ondansetron or any of the ingredients listed toward the end of this leaflet (see "Ingredients");**
- **you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe;**
- **the expiry date printed on the pack has passed; or**
- **the packaging is torn or shows signs of tampering.**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines;**
- **you have had to stop taking another medicine for your nausea or vomiting;**
- **you are taking any other medicines, including medicines you buy without a prescription;**

- **you have or used to have liver problems; or**
- **you are breastfeeding, pregnant or trying to become pregnant.**

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking APX-ONDANSETRON with other medicines.

How to take it

How much to take

Take APX-ONDANSETRON as directed by your doctor or pharmacist.

Do NOT take MORE TABLETS than your doctor or pharmacist tells you.

Do NOT take the tablets MORE OFTEN than your doctor or pharmacist tells you.

If you vomit within one hour taking your first APX-ONDANSETRON tablet of each course prescribed to you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take APX-ONDANSETRON

Swallow each tablet with a drink of water. Do not crush the tablet. If you have trouble swallowing your tablet, please tell your doctor.

How long to take APX-ONDANSETRON for

Do not stop taking APX-ONDANSETRON, or change the

dose without first checking with your doctor.

If you forget to take APX-ONDANSETRON

If you miss your dose and you do not feel sick, take your next dose when you are meant to

If you miss your dose and you feel sick, take the missed dose as soon as possible, then go back to taking APX-ONDANSETRON as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you or anyone else may have taken too much APX-ONDANSETRON, even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

While you are taking it

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use APX-ONDANSETRON to treat any other complaints unless your doctor says so.

Side effects

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking APX-ONDANSETRON, even if the problem is not listed below.

Like other medicines, APX-ONDANSETRON can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- headache;
- a sensation of warmth or flushing;
- mild stomach cramps;
- constipation or diarrhoea;
- dry mouth; or
- hiccups.

These are all mild side effects.

There is no immediate reason to stop taking your tablets unless you are concerned.

Tell your doctor immediately if you notice any of the following:

- 'wheezy' symptoms;
- chest pain or tightness of the chest;
- changes in the way your heart beats, e.g. if you notice it beating faster or slower than normal, or if it beats irregularly or if it 'throbs';
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness);
- patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when APX-ONDANSETRON is taken in combination with other serotonergic drugs. Serotonergic drugs can include certain types of antidepressants, opioid pain medicines such as tramadol and fentanyl, and lithium.

Please note, this is not an exhaustive list. Please discuss with your pharmacist or doctor if you have any concerns;

- severe skin reaction where the top layer of the skin detaches from the lower layers;
- low blood pressure;
- fits or convulsions;
- swelling of the eyelids, face, lips, mouth or throat which may cause difficulty in swallowing or breathing; or
- skin rash, skin lumps or hives.

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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them. If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where APX-ONDANSETRON has been used, blood vessel blockage has occurred.

However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when APX-ONDANSETRON has NOT been used. Discuss this with your doctor if you have any concerns.

If you feel unwell or have any symptoms that you do not understand, you should tell your doctor immediately.

After taking it

Storage

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep APX-ONDANSETRON in a cool, dry place where it stays below 25°C.

Do not leave in a car, on window sill or in bathroom.

Keep APX-ONDANSETRON in their blister pack until time to take.

Return any unused or expired medicine to your pharmacist.

- The 8 mg tablet also contains Opadry yellow 03K52033.

This medicine contains sugars as lactose.

*Some of these pack sizes are not marketed.

Please read this leaflet carefully before you start taking APX-ONDANSETRON. You may wish to keep it to read again.

Product description

What it looks like

APX-ONDANSETRON 4 & 8 (4 & 8 mg ondansetron as hydrochloride dihydrate) are presented in pack sizes* of 4, 10, 30 & 90 tablets in blister.

APX-ONDANSETRON 4 (AUST R 173184)

White to off-white, oval shaped, film-coated tablets debossed with 'E' on one side and '01' on the other side.

APX-ONDANSETRON 8 (AUST R 173182)

Yellow coloured, oval shaped, film-coated tablets debossed with 'E' on one side and '02' on the other side.

Do NOT use your tablets if they have changed colour.

Ingredients

Active Ingredient:

Ondansetron hydrochloride dihydrate

Each tablet contains either 4 mg or 8 mg of ondansetron.

Other Ingredients:

- Lactose anhydrous;
- Cellulose microcrystalline;
- Magnesium stearate;
- Starch-pregelatinised maize;
- The 4 mg tablet also contains glycerol triacetate, titanium dioxide and Hypromellose;

Sponsor/Marketing Authorisation Holder

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This leaflet was prepared in September 2021.