

ONDANOV TABLET

Ondansetron (4mg, 8mg)

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What ONDANOV Tablet used for

ONDANOV Tablet is used to manage of nausea (feeling sick) and vomiting (being sick) induced by cytotoxic chemotherapy and radiotherapy and for the prevention and treatment of postoperative nausea and vomiting.

How ONDANOV Tablet works

This medicine contains ondansetron, which belongs to a group of medicines called anti-emetics, which help to stop you feeling or being sick.

Before you use ONDANOV Tablet

When you must not use it

- Do not take if you are hypersensitivity to any component of ONDANOV Tablet.
- Do not take if you are taking Parkinson's disease medicine (Apomorphine hydrochloride)

ONDANOV is not recommended for use during pregnancy.

- Tell your doctor if you are pregnant or planning to become pregnant.
- ONDANOV may harm your unborn baby.
- If you do become pregnant during treatment with ONDANOV, tell your doctor.

If you are a woman of childbearing age, your doctor will check if you are pregnant and perform a pregnancy test if necessary before starting treatment with ONDANOV. If you may become pregnant, you should use effective birth control during treatment and for at least 2 days after stopping ONDANOV. Ask your doctor about options of effective birth control.

Before you start to take it

Ondansetron is known to increase large bowel transit time if you have a blockage of your intestines or constipation, as you will need to be closely monitored by your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular it is important to tell your doctor if you are taking any of the following medicines:

- Phenytoin
- Carbamazepine
- Rifampicin (an antibiotic).
- Tramadol

How to take ONDANOV Tablet

How much to take

To prevent nausea and vomiting from chemotherapy or radiotherapy

On the day of chemotherapy or radiotherapy

- The usual adult dose is 8 mg taken one to two hours before treatment and another 8 mg twelve hours after.

On the following days

- the usual adult dose is 8 mg twice a day
- this may be given for up to 5 days.

Children aged 3-17 years and adolescents:

The doctor will decide the dose depending on the child's size (body surface area) or weight. Look at the label for more information.

- the usual dose for a child is up to 4 mg twice a day
- this can be given for up to 5 days.

To prevent nausea and vomiting after an operation

The usual adult dose is 16 mg before your operation

Children aged 3-17 years and adolescents:

It is recommended that ondansetron is given as an injection.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

Ondansetron tablets should start to work within one or two hours of taking a dose.

When to take it

Use as directed by your doctor or pharmacist.

How long to take it

Continue taking ONDANOV for as long as your doctor recommends.

If you forget to take it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think

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you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using ONDANOV Tablet

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking ONDANOV Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ONDANOV Tablet to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

This medicine does not affect your ability to drive or use machines.

Side effects

Like all medicines, ONDANOV Tablet can cause side effects, although not everybody gets them.

You may get these side effects while taking ONDANOV Tablet.

- Headache
- a sensation of warmth or flushing
- hiccups
- constipation
- sudden skin rash, difficulty breathing, and fainting (within minutes to hours) due to hypersensitivity (anaphylactic shock)

- Fits (seizures).

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://npra.gov.my> (Consumers → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccine (AEFI).

Storage and disposal of ONDANOV Tablet

Storage

Keep out of the reach and sight of children.

Protect from light

Do not store above 30°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

ONDANOV 4mg Tablet:

Orange, round, shallow and convex film coated tablet with breakline on one side.

ONDANOV 8mg Tablet:

Orange, round, shallow and convex film coated tablet with no breakline on one side.

4mg and 8mg tablet have different diameter and thickness.

Ingredients

- Active ingredient

ONDANOV 4mg Tablet:

Each film-coated tablet contains 5 mg Ondansetron Hydrochloride Dihydrate equivalent with 4 mg of Ondansetron.

ONDANOV 8mg Tablet:

Each film-coated tablet contains 10 mg Ondansetron Hydrochloride Dihydrate equivalent with 8 mg of Ondansetron.

- Excipients:

Lactose, Microcrystalline Cellulose, Crospovidone, Povidone, Colloidal Silicon Dioxide, Magnesium stearate, Ethanol, Purified Water, Macrogol Poly(vinylalcohol) Grafted Copolymer, Talc, Titanium Dioxide, FDC Yellow No.6 Al Lake, Purified Water

MAL No:

ONDANOV 4mg Tablet:

MAL18016025AZ

ONDANOV 8mg Tablet:

MAL18016033AZ

Manufacturer

Pt Novell Pharmaceutical Laboratories.
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Product Registration Holder

Averroes Pharmaceutical Sdn. Bhd
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