

Patient Information Leaflet:

ONDEMET 4MG & 8MG TABLETS (Ondansetron)

Read all of this leaflet carefully before you start taking/using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. *What Ondemet is and what it is used for*
2. *Before you take/use Ondemet*
3. *How to take/use Ondemet*
4. *Possible side effects*
5. *Storing Ondemet*

The name of this medicine is Ondemet 4mg Tablets or Ondemet 8mg Tablets (referred to as Ondemet throughout this leaflet).

Marketing Authorisation Holder:

Beacon Pharmaceuticals Ltd., The Regent, The Broadway, Crowborough, East Sussex, TN6 1DA, UK.

Manufacturer:

Pharmathen S.A., 6 Dervenakion Str., Pallini 153 51, Attikis, Greece.

1. What Ondemet is and what it is used for

Ondemet tablets are film-coated tablets for oral use. They contain the active ingredient ondansetron.

Each pale yellow, film-coated tablet contains 4mg or 8mg of the active ingredient ondansetron as hydrochloride dihydrate. The 4mg tablet has '41' embossed on one side.

The 8mg tablet has '42' embossed on one side

Other ingredients in Ondemet Tablets are lactose monohydrate, microcrystalline cellulose, pregelatinised starch and magnesium stearate.

The tablets are coated with Opadry Yellow which contains hypromellose, hydroxypropyl cellulose, propylene glycol, sorbitan oleate, sorbic acid, vanillin, titanium dioxide (E171) and quinoline yellow (E104).

Each pack of Ondemet 4mg Tablets contains 10, 50 or 100 tablets in blisters.

Each pack of Ondemet 8mg Tablets contains 10, 15, 30, 50 or 100 tablets in blisters.

Ondansetron is one of a group of medicines called anti-emetics.

Ondemet Tablets are used in children over 2 years, adolescents and adults (including the elderly) to treat nausea (feeling sick) and vomiting (being sick) caused by chemotherapy or radiotherapy. It is also used to prevent nausea and vomiting in patients following an operation.

2. Before you take/use Ondemet

Ondemet should NOT be used if:

- You have ever had an allergic reaction to ondansetron or to other similar anti-emetics (e.g. granisetron, dolasetron) or to any of the other ingredients.

Before taking Ondemet, tell your doctor if:

- You have a sensitivity to similar medicines to Ondemet.
- You have a blockage in your gut
- You are due to have surgery to the adenoids or tonsils
- You have a heart problem or are taking medicines used to treat a heart problem
- You have liver problems
- You have been told by your doctor that you have an intolerance to some sugars
- Your child is being treated and he/she is very small or is younger than 2 years old

Consult your doctor or pharmacist if these statements were applicable to you at any time in the past.

Taking Ondemet with other medicines

Tell your doctor if you are taking any of the following medicines:

- Phenytoin (used to treat epilepsy and heart arrhythmias), Carbamazepine (used to treat epilepsy and neuralgic pain) or Rifampicin (an antibiotic), as these medicines may reduce the effect of ondansetron
 - Tramadol (used to treat pain following surgery), as the effect of this medicine may be reduced by ondansetron
- Tell your doctor if you are taking any other medicine including those that you have bought.

Pregnancy and breast feeding

It is not recommended that Ondemet be taken during pregnancy. If it is absolutely necessary it should be given with caution especially in the first trimester.

If you are taking Ondemet you should not breast-feed your baby

Driving and using machines

Ondemet is unlikely to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Ondemet

Ondemet tablets contain lactose monohydrate. If you have an intolerance to some sugars you should tell your doctor before taking this medicine.

3. How to take/use Ondemet

Your doctor will have decided the number of tablets of Ondemet for you to take, so follow his or her instructions.

Treatment of nausea and vomiting in patients receiving chemotherapy or radiotherapy

For patients receiving chemotherapy or radiotherapy ondansetron can be given orally as tablets or by injection or infusion into a vein. The dose of Ondemet will depend on the dose and combination of chemotherapy and radiotherapy given.

For most patients ondansetron should be given initially by injection into a vein immediately before treatment, followed by 8mg orally every 12 hours.

Oral administration: 8mg taken 1-2 hours before treatment, followed by 8mg 12 hours later.

To protect against delayed or prolonged vomiting after the first 24 hours, oral treatment with Ondemet Tablets should be continued for up to 5 days after a course of treatment. The recommended dose for oral administration is 8mg twice daily.

Treatment of severe nausea and vomiting in patients receiving chemotherapy

To protect against delayed or prolonged vomiting after the first 24 hours, oral treatment with Ondemet Tablets should be continued for up to 5 days after a course of treatment. The recommended dose for oral administration is 8mg twice daily.

Children (aged 2 years and over) and adolescents (under 18 years old): Ondansetron may be given as a slow injection into a vein over 15 minutes immediately before chemotherapy, followed by a 4mg dose taken orally 12 hours later. Oral treatment should be continued for up to 5 days after a course of treatment. The dose given will depend on the size of the child and will be worked out by the doctor.

Ondemet should not be given to children under 2 years or children who are very small.

The elderly (over 65 years): Ondansetron is well tolerated in this patient group and no special dosing instructions are required.

Prevention of nausea and vomiting after an operation

Adults: 16mg to be taken one hour before anaesthesia or 8mg taken one hour before anaesthesia followed by two further doses of 8mg at 8 hourly intervals.

Treatment of established nausea and vomiting in patients after an operation

For the treatment of established nausea and vomiting following an operation ondansetron given as a slow injection into a vein is recommended.

Patients with moderate or severe liver problems

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

If you have the impression that the effect of Ondemet is too strong or too weak, talk to your doctor or pharmacist.

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 two doses at the same time.

If you have taken too many tablets talk to your doctor or pharmacist immediately.

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

REMEMBER –this medicine has been prescribed for you. Never give it to anyone else even if they have the same symptoms as it may harm them.

4. Possible side effects

Like all medicines, Ondemet may cause side effects.

A few people can be allergic to some medicines. If any of the following happen, stop taking Ondemet and tell your doctor immediately or go to the casualty department of the nearest hospital:

- Severe itching of the skin, rash
- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulties in swallowing or breathing.
- Collapse

You may have had a serious allergic reaction to Ondemet.

All of these are very serious side effects and are rare

Tell your doctor if you notice any of the following:

Side effects that are very common:

- Headache

Side effects that are common:

- Constipation
- Local burning sensation following insertion of suppositories
- Sensation of flushing and warmth

Side effects that are uncommon:

- Hiccups
- Low blood pressure
- Chest pains or palpitations
- Slowing of the heart rate
- Seizures
- Upward movement of the eyes
- Abnormal body movements or shaking
- An increase in liver function tests (commonly seen in patients receiving chemotherapy with cisplatin)

Side effects that are rare:

- Dizziness (during rapid injection into a vein)
- Muscle cramps
- Visual disturbances e.g. blurred vision (mainly during rapid injection into a vein)

Side effects that are very rare:

- Temporary blindness (mainly during injection into a vein and in patients receiving chemotherapy e.g. cisplatin)

If you do experience side effects these usually disappear after a few days of treatment. If they are troublesome or persistent, or if you have side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. Storing Ondemet

There are no special storage instructions.

Keep out of the reach and sight of children.

Use by date:

Do not use Ondemet after the expiry/use before date on the blister and carton.

Further information:

This leaflet does not include all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

If you have any medicine left over at the end of your treatment, please return this to your pharmacy who will dispose of it safely.

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