

Package Leaflet: Information for the User
Ametron Melt 4mg & 8mg oral lyophilisate
Ondansetron

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions about your illness or your medicine, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Ametron Melt is and what it is used for

Ametron Melt contains a medicine called ondansetron. This belongs to a group of medicines called antiemetics. Ametron Melt is a special type of Ondansetron tablet that dissolves very quickly when put on top of the tongue.

Ametron Melt is used for:

- managing nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- preventing nausea and vomiting after surgery (adults only).

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. What you need to know before you take Ametron Melt

Do not take Ametron Melt if:

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Ametron Melt (listed in Section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before taking Ametron Melt.

Warnings and precautions

Check with your doctor, nurse or pharmacist before taking Ametron Melt if:

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- you have liver problems
- you have a blockage in your gut
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking Ametron Melt.

Other medicines and Ondansetron

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Ondansetron can affect the way some medicines work. Also some other medicines can affect the way Ondansetron works.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- carbamazepine or phenytoin used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer.
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines and trastuzumab)
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine,

- paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Ametron Melt.

Tell your doctor or pharmacist immediately if you get any of these symptoms during and after the treatment with Ametron Melt.

- If you experience sudden chest pain or chest tightness (myocardial ischemia).

Pregnancy and breast-feeding

Only use during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. This is because Ondansetron can slightly increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth). If you are already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron. If you are a woman of childbearing potential you may be advised to use effective contraception.

Do not breast-feed if you are taking Ondansetron. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Important information about some of the ingredients of Ametron Melt

- Ametron Melt 4 mg contains 1.50 mg aspartame per tablet.
Ametron Melt 8 mg contains 1.50 mg aspartame per tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Speak to your doctor before taking this medicine.

3. How to take Ametron Melt

Always take Ametron Melt exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

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 or 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 over 6 months 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 over 1 month 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.

Ametron Melt should start to work within one or two hours of taking a dose.

If you are sick (vomit) within one hour of taking a dose

- take the same dose again
- otherwise, do not take more Ametron Melt than the label says.

If you continue to feel sick, tell your doctor or nurse.

If you take more Ametron Melt than you should

If you or your child take more Ondansetron than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Ametron Melt

If you miss a dose and feel sick or vomit:

- take a Ametron Melt as soon as possible, then
- take your next tablet at the usual time (as shown on the label)
- do not take a double dose to make up for a forgotten dose.

If you miss a dose but do not feel sick

- take the next dose as shown on the label
- do not take a double dose to make up for a forgotten dose.

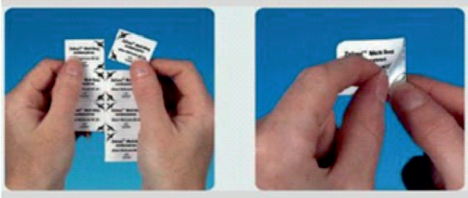
If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

How to remove Ondansetron from the blister and take the medicine

Do not take Ondansetron tablet out from its blister until you are ready to take it. Before you take the Ondansetron make sure the foil packaging has not been pierced.

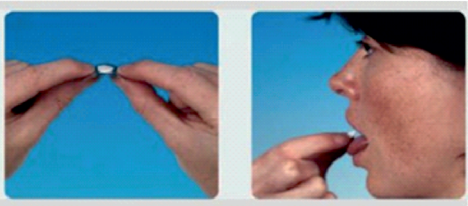
Important: Do not try to push Ondansetron through the foil top like a usual tablet. This is because Ondansetron is fragile and will break.

- Tear off one Ondansetron in its blister.
- Peel back the foil.
- Gently push out the Ondansetron tablet.
- Place the Ondansetron on top of the tongue. It will dissolve very quickly. Then you can swallow as normal.



1. Tear off one ondansetron in its blister.

2. Peel back the foil as shown.



3. Gently push out the Ondansetron Tablet

4. Place the Ondansetron on top of the tongue. It will dissolve very quickly and then swallows as normal

4. Possible side effects

Like all medicines, Ametron Melt can cause side effects, although not everybody gets them.

Some side effects could be serious

Stop taking Ametron Melt and seek medical help immediately if you or your child experience any of the following:

Allergic reactions

- 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

Myocardial ischemia

Signs include:

- sudden chest pain or
- chest tightness

Other side effects include:

Very common (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
- changes to liver function test results (if you take Ametron Melt with a medicine called cisplatin, otherwise this side effect is uncommon).

Uncommon (may affect up to 1 in 100 people)

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat
- chest pain
- fits
- unusual body movements or shaking.

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

- feeling dizzy or light headed
- 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 comes back within 20 minutes.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ametron Melt

- Keep this medicine out of the sight and reach of children.
- Do not use Ametron Melt after the expiry date (Shelf life : 2 years) which is stated on the pack after 'Exp'. The expiry date refers to the last day of that month.
- Store Ametron Melt: This medicinal product does not require any special storage conditions
- Ametron Melt should only be taken out of the blister immediately before taking it.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If your medicine shows any signs of discolouration or deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Ametron Melt contains

- The active ingredient is ondansetron. Each Ametron Melt contains ondansetron 4 mg or 8 mg.
- The other ingredients are pullulan (E1204), mannitol (E421), aspartame (E951), polysorbate 80 (E433), strawberry flavour. *Contains Maize maltodextrin, Flavouring substances, Triethyl citrate (E1505), Propylene glycol (E1520), Flavouring preparations.

What Ametron Melt looks like and contents of the pack

Oral lyophilisate.

Blister packaging in packs of 10 tablets

The blister comprising PVC/polyamide/ aluminium blister with peel-off lidding of paper/PET/aluminium foil.



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