Package leaflet: Information for the patient

Emizof 4 mg Film-coated Tablets
Emizof 8 mg Film-coated Tablets

Ondansetron

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Emizof is and what it is used for

Ondansetron belongs to a group of medicines known as anti-emetics or anti-sickness medicines.
Emizof is used for:
- preventing nausea (feeling sick) and vomiting (being sick) caused by chemotherapy or radiotherapy treatment for cancer (in adults and children aged 6 months or over).
- 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 Emizof

Do not take Emizof:
- if you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to anti-sickness medicines belonging to the group selective serotonin (5-HT_3)-receptor antagonists (e.g. granisetron, dolasetron), because in such a case you may also be allergic to ondansetron.
- if you are taking apomorphine (used to treat Parkinson's disease).

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

Warnings and precautions
Talk to your doctor, nurse or pharmacist before taking Emizof:
- if you have ever had heart problems or you have an uneven heart beat (arrhythmias)
- if you have problems with the levels of salts in your blood such as potassium, sodium or magnesium.
- if you have a blockage in your gut or you suffer from severe constipation.
- if you are going to have, or have recently had, your tonsils or adenoids removed, because treatment with ondansetron may hide signs of internal bleeding.

- if you have liver problems.

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

Other medicines and Emizof

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

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

- apomorphine (a medicine used to treat Parkinson's disease), as significantly reduced blood pressure and loss of consciousness have been reported when apomorphine and ondansetron are used at the same time
- carbamazepine or phenytoin used to treat epilepsy. These medicines can reduce the effect of ondansetron.
- rifampicin used to treat infections such as tuberculosis (TB). This can reduce the effect of ondansetron.
- antibiotics such as erythromycin or ketoconazole used to treat fungal infections
- anti-arrhythmic medicines (such as amiodarone) used to treat an uneven heartbeat
- beta-blocker medicines (such as atenolol or timolol) used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer. The effect of this medicine may be reduced.
- cancer medicines (especially anthracyclines and trastuzumab)
- certain types of medicines used to treat depression known as SSRIs (selective serotonin reuptake inhibitors) or SNRIs (serotonin and noradrenaline reuptake inhibitors) as these may cause serotonin syndrome, a potentially life-threatening reaction, when used together with ondansetron. The symptoms of serotonin syndrome may include a combination of the following: nausea (feeling sick), vomiting, agitation, diarrhoea, high temperature, increased blood pressure, excessive sweating, rapid heartbeat, hallucinations, loss of coordination, overactive reflexes and coma.

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

Pregnancy and breast-feeding

You should not use Emizof during the first trimester of pregnancy. 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, nurse or pharmacist for advice before taking Emizof.

If you are a woman of childbearing potential you may be advised to use effective contraception.

Do not breast-feed if you are taking Emizof. This is because this medicine can pass into the mother's milk. Ask your doctor, pharmacist or midwife for advice.

Driving and using machines

It is not expected that Emizof will affect your ability to drive; however, if any of the side effects (listed in section 4) affect you (e.g. dizziness, blurred vision) caution is advisable. **Do not drive or operate machines if you are feeling unwell.**

Emizof contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Emizof

Always take this medicine exactly as your doctor has told you. 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 and radiotherapy treatment
On the day of chemotherapy and radiotherapy
- the recommended adult dose is 8 mg taken one or two hours before treatment and another 8 mg twelve hours after.

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

Use in children (aged 6 months or over) and adolescents
The doctor will decide the dose. See the label for more information.
- the recommended dose for a child is up to 8 mg twice a day depending on the weight of the child.
- this can be given for up to 5 days.

To prevent nausea and vomiting after an operation
The recommended adult dose is 16 mg before your operation or
- 8 mg before an operation, then
- 8 mg after the operation, then
- 8 mg after further 8 hours.

Use in children (aged 1 month or over) and adolescents
It is recommended that Emizof is given as an injection. Other forms of this medicine are more suitable for children; ask your doctor or pharmacist.

Elderly
There is limited experience with the use of ondansetron in elderly patients for the prevention of nausea and vomiting after an operation. However ondansetron is well tolerated in patients over 65 years of age receiving chemotherapy. Alteration to the dosage is not required.

Patients with moderate or severe liver problems
The total daily dose should not be more than 8 mg.
Emizof should start to work within one or two hours of taking a dose.

Patients with kidney problems or poor sparteine/debrisoquine metabolism
Patients with kidney problems or who cannot metabolise sparteine/debrisoquine well can take the recommended doses of ondansetron, as detailed above.

If you are sick (vomit) within one hour of taking a dose
- take the same dose again
- otherwise do not take more Emizof tablets than the label says.

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

Method of administration
- Swallow the tablets with a glass of water.
- Ondansetron is also available as an injection.

If you take more Emizof than you should
If you or your child take more Emizof than you should, talk to a doctor or go to a hospital straight away. Take the container and any remaining tablets with you.

There is limited information about overdose with ondansetron. Signs of overdose that have been reported include disturbances of vision, severe constipation, low blood pressure, fainting and disturbances in heart beat rhythm. In young children this may also include fever, sweating, dilated pupils and diarrhoea.

If you forget to take Emizof
If you miss a dose **and** feel sick or vomit:
- take Emizof 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following serious side effects may occur when taking this medicine. If you notice any of these, stop taking the medicine and see a doctor straight away or go to the nearest hospital immediately.

Rare (may affect up to 1 in 1,000 people)
- If you have an allergic reaction, the signs may include:
- 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.

Uncommon (may affect up to 1 in 100 people)
- Involuntary eye movements (oculogyric crisis)

Very rare (may affect up to 1 in 10,000 people)
- serious widespread rash with blisters and extensive peeling of the skin, particularly around the mouth, nose, eyes and genitals, which resembles severe burns

Other possible side effects

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

Uncommon (may affect up to 1 in 100 people)
- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat or slow heart beat
- chest pain with or without ECG changes

- fits, unusual body movements or shaking
- changes to blood tests which show changes in the way the liver is working (most often in patients receiving chemotherapy with cisplatin)

Rare (may affect up to 1 in 1,000 people)
- transient blurred vision
- disturbances in heart rhythm called QT prolongation (delayed conduction of electrical signals which can be seen on an ECG, an electrical recording of the heart). In some people this can develop into a potentially serious heart condition known as Torsades de Pointes. This can result in a very fast heartbeat 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.

Unknown (cannot be estimated from the available data)
- myocardial ischemia – signs include sudden chest pain or chest tightness

Side effects in children and adolescents
The side effects reported in children and adolescents were similar to that seen in adults, as listed above.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emizof

Keep this medicine out of the sight and reach of children.

Do not store tablets above 30°C.

Do not use this medicine after the expiry date which is stated on the carton or blister foil after EXP. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Emizof contains

The active substance is ondansetron hydrochloride dihydrate.
Each tablet contains either 4 mg or 8 mg of the active ingredient ondansetron (as the hydrochloride dihydrate).

The other ingredients are lactose monohydrate (see section 2 “Emizof contains lactose”), microcrystalline cellulose (E460), pregelatinised maize starch, magnesium stearate (E572). The coating contains hypromellose (E464), titanium dioxide (E171), macrogol (E1520), hydroxypropyl cellulose (E463), sorbitan oleate (E494), sorbic acid (E200), vanillin and Quinoline yellow (E104).

What Emizof looks like and contents of the pack
Emizof are round, pale yellow film-coated tablets. The 4 mg strength tablets are marked “41” on one side and the 8 mg strength are marked “42” on one side.

Emizof is available in blister packs of 3, 6, 10, 14, 15, 20, 30, 40, 50, 60, 90, 100, 200, 300, 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd,
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35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland

Manufacturer(s)

McDermott Laboratories Ltd,
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35/36 Baldoyle Industrial Estate,
Grange Road,
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Mylan Hungary Kft., Mylan utca 1., Komárom, H-2900, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Greece:	Ondanserton/Generics F.C. TAB 8 mg/TAB
Ireland:	Emizof 4 mg Film-Coated Tablets & Emizof 8 mg Film-Coated Tablets
Netherlands:	Ondansetron Mylan 4 mg, filmomhulde tabletten & Ondansetron Mylan 8 mg, filmomhulde tabletten
Portugal:	Ondansetron Mylan 4 mg Comprimidos revestidos por película & Ondansetron Mylan 8 mg Comprimidos revestidos por película
Spain:	Ondansetron Viatris 4 mg comprimidos recubiertos con película EFG & Ondansetron Viatris 8 mg comprimidos recubiertos con película EFG
United Kingdom:	Ondansetron 4 mg Film coated Tablets & Ondansetron 8 mg Film coated Tablets

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