Package leaflet: Information for the user

Emigo®-MD Tablets

(Ondansetron IP 4 mg Mouth Dissolving Tablet)

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 or pharmacist or nurse.
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Emigo®-MD Tablet is and what it is used for
2. What you need to know before you take Emigo®-MD Tablet
3. How to take Emigo®-MD Tablet
4. Possible side effects
5. How to store Emigo®-MD Tablet
6. Contents of the pack and other information

1. What Emigo®-MD Tablet is and what it is used for

Emigo®-MD tablets are Mouth Dissolving (orally disintegrating) Tablets and contain a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. Ondansetron works by blocking signals in the brain that cause nausea and vomiting. Emigo®-MD Tablet are a special type of tablet that dissolves very quickly when put on top of the tongue. Ondansetron orally disintegrating Tablets are used for:

- preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer.
- preventing nausea and vomiting after surgery.

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 Emigo®-MD Tablet

Do not take Emigo®-MD Tablet, if

- You are taking apomorphine (used to treat Parkinson's disease).

- You are allergic to ondansetron or any of the other ingredients of this medicine

If you are not sure, talk to your doctor, nurse, or pharmacist before taking Emigo®-MD Tablet.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Emigo®-MD Tablets if:

- you are allergic to medicines similar to ondansetron known as 5HT3 antagonists such as granisetron or palonosetron.
- you suffer from severe constipation, or have you been told you have a blockage in your gut.
- 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 suffer from any liver problems.
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- if you have had an operation to remove both the adenoids and tonsils (adenotonsillar surgery).

If you are not sure if any of the above apply to you, talk to your doctor, nurse, or pharmacist before taking Emigo®-MD Tablets.

Other medicines and Emigo®-MD Tablets

Tell your doctor 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 ondansetron can affect the way some medicines work. Also some other medicines can affect the way ondansetron works.

Emigo®-MD Tablets may have an effect on other drugs or other drugs may have an effect on Emigo®-MD Tablets.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

- Anti-arrhythmic medicines such as amiodarone used to treat an uneven heartbeat.
- Phenytoin or carbamazepine, used to treat epilepsy.
- Rifampicin, an antibiotic used to treat infections.
- Antibiotics such as erythromycin or ketoconazole.
- Tramadol, a pain relieving medicine.
- Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines.

- 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.

Contact your doctor. It may be necessary to adjust the dose.

Emigo®-MD Tablets with food and drink

You may take Ondansetron tablets with food and drinks. The tablets should be taken with a glass of water.

Children and adolescents

Children receiving Emigo®-MD Tablets with drugs that are harmful to liver should undergo regular check-up for liver problems.

Pregnancy and breast-feeding

If you are already pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are a woman of childbearing potential, you may be advised to use effective contraception.

Pregnancy

You should not use Emigo®-MD Tablets during the first trimester of pregnancy. This is because Emigo®-MD Tablets 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).

Breast-feeding

Do not take Emigo®-MD Tablets if you are breast-feeding, because it is excreted into the milk.

Driving and using machines

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

3. How to use Emigo®-MD Tablets

Always take Emigo®-MD Tablets 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 or radiotherapy

On the day of chemotherapy or 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.

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 recommended 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 or

- 8 mg before the operation, then
- 8 mg after the operation, then
- 8 mg after a further eight hours.

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.

Emigo®-MD Tablets 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 Emigo®-MD tablets than the label says.

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

If you take more Emigo®-MD Tablets than you should

If you or your child take more Emigo®-MD Tablets 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 Ondansetron Tablets

If you miss a dose and feel sick or vomit:

- Take Emigo®-MD Tablets 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 or pharmacist.

4. Possible side effects

Like all medicines, Emigo®-MD can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, stop taking it and see a doctor straight away. 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

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 EMIGO MD® Tablets 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
- Slower heart rate

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: Website: www.zuventus.co.in and click the tab "Safety Reporting" located on the top end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine. You can also report the side effect with the help of your treating physician.

5. How to store Emigo®-MD tablets

- Keep this medicine out of the sight and reach of children.
- Do not use Emigo®-MD Tablets after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.
- Store Emigo®-MD Tablets in the original blister to protect from light and moisture.
- Emigo®-MD Tablets should only be taken out of the blister immediately before taking them.
- If your doctor tells you to stop taking Emigo®-MD Tablets, it is important to return any which are left over to your pharmacist.
- 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

Emigo®-MD Tablets

Each uncoated mouth dissolving tablet contains:

Ondansetron IP …… 4 mg.

Excipients ……..…….... q.s.

Colour: Lake Erythrosine.

What Emigo®-4 looks like and contents of the pack Film-coated tablet.

Emigo®-4 contains 10 blister strips of 10 tablets each.

Marketing Authorisation Holder

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