Package leaflet: Information for the user

Emigo®-4

(Ondansetron Tablets IP 4 mg)

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What EMIGO® is and what it is used for

The active ingredient in **Emigo®-4** tablets, ondansetron, belongs to a group of medicines called anti-emetics.

Emigo®-4 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®-4

Do not take Emigo®-4 if

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

- you have ever had any allergic (hypersensitive) reaction with other anti-emetics (for example granisetron or dolasetron)
- you are taking apomorphine (used to treat Parkinson's Disease)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking **Emigo®-4**:

- if you have a blockage in your gut or suffer from severe constipation • if you are due to have surgery to the adenoids or tonsils
- if you have a heart problem (e.g. congestive heart failure which causes shortness of breath and swollen ankles).
- if you have an uneven heart beat (arrhythmias)
- if you have liver problems
- if you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If any of the above apply, you should inform your doctor before beginning treatment with **Emigo®-4**.

Other medicines and Emigo®-4

Emigo®-4 may have an effect on other drugs and other drugs may have an effect on Emigo®-4.

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

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

- Medicines used to treat epilepsy (phenytoin, carbamazepine)
- Rifampicin (used to treat infections such as tuberculosis (TB) an antibiotic).
- Tramadol (a medicine used to treat pain)
- medicines that affect the heart (such as haloperidol or methadone)
- Medicines used to treat heart problems such as abnormal heart beats (anti-arrhythmic like amiodarone) and/or high blood pressure (beta-blockers like atenolol, timolol)
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- cancer medicines (especially anthracyclines such as doxorubicin, daunorubicin and monoclonal antibodies such as trastuzumab) as these may interact with **Emigo®-4** to cause heart arrhythmias
- antibiotics (such as erythromycin or ketoconazole),

- 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.

Pregnancy, breast-feeding and fertility

Pregnancy:

You should not use Emigo®-4 during the first trimester of pregnancy. This is because Emigo®-4 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 Emigo®-4. It is recommended that sexually active women of childbearing potential use effective contraception (methods resulting in less than 1% pregnancy rate) during treatment with Emigo®-4.

Breast-feeding:

You should not breast-feed your infant whilst taking Emigo®-4. Ask your doctor or pharmacist for advice before taking any medicine.

Fertility: There are no data on the effects of Emigo®-4 on fertility in humans.

Driving and using machines

Emigo®-4 is unlikely to affect your ability to drive or operate machinery.

3. How to use Emigo®-4

Always take EMIGO® 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®-4 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®-4** than the label says.

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

If you take more Emigo®-4 Tablets than you should

If you or your child take more Emigo®-4 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®-4 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®-4** Tablets can cause side effects, although not everybody gets them.

If any of the following effects happen, stop taking your tablets and tell your doctor immediately:

• An **allergic** reaction. The symptoms may include:

- Sudden wheezing and chest pain or tightness
- Swelling of the eyelids, face, lips, mouth tongue or throat
- Difficulty breathing
- Collapse
- Skin rash- red spots or lumps under your skin (hives) anywhere on your body

• Fits (seizures)

• Chest pain

• Temporary loss of vision which usually comes back within 20 minutes

Side effects of Emigo®-4

If you are concerned about any side effects, please talk to your doctor. If any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Very common (may affect more than 1 in 10 people):

• Headache

Common (may affect up to 1 in 10 people):

• Sensation of flushing and warmth • Constipation

• Local burning sensation (following insertion of suppositories).

• Local IV injection site reactions

Uncommon (may affect up to 1 in 100 people):

• uncontrollable movements of the body, including upward rolling movement of the eyeballs

• Fits (seizures). **If this should occur seek urgent medical attention**

• Dizziness (during rapid IV administration)

• Irregular heartbeat, fast or slow heart rate

• Chest pain. **If this should occur seek urgent medical attention.**

• Low blood pressure

• Hiccups

• An increase in liver function test results (most often in patients receiving chemotherapy with cisplatin)

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

• An immediate allergic reaction, which may be serious and include symptoms such as sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse, skin rash. **If this should occur, seek urgent medical attention.**

- Visual disturbances e.g. blurred vision (though this has almost always been associated with an EMIGO® injection rather than tablets).
- Effects on heart rhythms that can be seen on an ECG (an electrical trace of your heart). Symptoms may include feeling lightheaded or loss of consciousness.

Very rare (may affect up to 1 in 10,000 people):

- Temporary loss of vision which usually comes back within 20 minutes. **If this should occur seek urgent medical attention**. Temporary loss of vision has almost always been reported with Emigo® injection, rather than tablets, and usually when given with chemotherapy containing cisplatin.

Not known (cannot be estimated from the available data) Myocardial ischemia Signs include:

- sudden chest pain or
- chest tightness

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®-4

- Keep this medicine out of the sight and reach of children. This medicine does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the blister and carton 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 Emigo®-4 contains

The active substance is ondansetron hydrochloride IP.

Emigo®-4

Each film coated tablet contains:

Ondansetron Hydrochloride IP

equivalent to Ondansetron …… 4 mg.

Excipients …… q.s.

Colour: Titanium Dioxide IP.

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

Emigo®-4 contains pack of 10 tablets.

Marketing Authorisation Holder

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Zuventus House, Plot Y2, CTS No.: 358/A2,

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Nahur (W), Mumbai 400 078, Maharashtra, India.

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