

Package Leaflet: Information for the User
Setofilm® 4 mg Orodispersible Films
Setofilm® 8 mg Orodispersible Films
Ondansetron 4 mg Orodispersible Films
Ondansetron 8 mg Orodispersible Films
(ondansetron)

Your medicine is known by the above names, but will be referred to as Setofilm® throughout this leaflet.

Read all of this leaflet carefully before you start using 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1 WHAT SETOFILM IS AND WHAT IT IS USED FOR

Setofilm® contains a medicine called ondansetron. This belongs to a group of drugs called antiemetics.

Setofilm® is used to treat and prevent nausea (feeling sick) and vomiting (being sick) caused by chemotherapy or radiotherapy. It can also be used after an operation to prevent and treat nausea and vomiting.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE SETOFILM

Do not use Setofilm®

- if you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other drugs belonging to the group of selective serotonin (5-HT₃)-receptor antagonists (eg. granisetron, dolasetron)
- if you are taking apomorphine (used to treat Parkinson's disease). For further information see section "Other medicines and Setofilm®".

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Setofilm® if:

- you have ever had heart problems
- you have an irregular or uneven heart beat (arrhythmia)
- you have liver problems
- you have a blockage in your gut or bowel or if you suffer from severe constipation
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium
- you are going to have or have recently had your tonsils or adenoids removed, because treatment with Setofilm® may hide symptoms of internal bleeding
- this medicine is prescribed for a child below the age of 2 years or with a body surface of less than 0.6m² and / or weighing 10kg and below
- you have depression or other conditions that are treated with antidepressant. The use of these medicines together with Setofilm can lead to serotonin syndrome, a potentially life threatening condition (see "Other medicines and Setofilm").

If you need to have a blood or urine test, you should tell the person performing the test that you are taking Setofilm®.

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

Other medicines and Setofilm®

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

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

- Apomorphine (a medical substance for the treatment of Parkinson's disease), as excessive drop in blood pressure and loss of consciousness have been reported when administering Setofilm® (Ondansetron) concomitantly with apomorphine.

- phenytoin, carbamazepine (medicines used to treat epilepsy)
- rifampicin (for treating serious bacterial infections, like TB)
- antibiotics such as erythromycin
- antifungal agents such as ketoconazole
- tramadol (for managing pain)
- anti-arrhythmics (used to treat irregular or fast heart beat)
- beta-blockers (used to treat certain heart or eye problems, anxiety or prevent migraines)
- medicines that can affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines and trastuzumab)
- antidepressants such as SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/ or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram; or
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine
- Buprenorphine/opioids (medicinal products used for the treatment of pain or dependency on narcotics).

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

Setofilm® with food and drink

You may take Setofilm® with food and drink.

Pregnancy and breast-feeding

Pregnancy:

Only use Setofilm® 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 Setofilm® 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 pregnant, think you may 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.

Breast-feeding:

You should not breast-feed whilst using Setofilm® as it can pass into your breast milk.

Driving and using machines

Setofilm® has little or no effect on your ability to drive or use machines.

3 HOW TO USE SETOFILM®

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, or pharmacist if you are not sure.

Setofilm® is for oral use only. It may be recommended for patients who may have problems with taking or swallowing tablets; for example children or elderly.

- Remove Setofilm® orodispersible film from each individual sachet taking care not to damage the film as follows: Open the sachet only at the tear tag and tear this off slowly. Do not cut the sachet.
- Before use check the film for damage as you should only use undamaged films.
- Ensure the mouth is empty (and your fingers are dry) before placing Setofilm® orodispersible film on to the tongue.
- The film should disintegrate on your tongue without water in a few seconds (in saliva which can be subsequently swallowed).

Treatment and prevention of sickness (nausea and vomiting) in patients receiving chemotherapy or radiotherapy

Elderly:

Setofilm® is well tolerated by elderly patients. They may take the same dosage as adults (see below).

Adults:

8 mg 1-2 hours before chemotherapy or radiotherapy, followed by 8 mg every 12 hours for up to 5 days. Your doctor may recommend that your first dose is given by injection.

Children (aged 6 months and over) and adolescents (<18 years):

Your doctor will recommend what dose of ondansetron should be given. The individualised dose will depend on the weight or body surface area of the child.

Prevention and Treatment of post-operative sickness (nausea and vomiting).

Elderly:

Ondansetron is well tolerated by elderly patients. They may take the same dosage as adults; see below.

Adults:

Take 16 mg of Setofilm® 1 hour before your operation or 8 mg administered one hour before your operation, followed by two further doses of 8 mg 8 hours apart as directed by your doctor.

Children aged over 4 years and adolescents:

In children weighing 40 kg and above, take 4mg of Setofilm® 1 hour before your operation, followed by one further dose of 4 mg after 12 hours.

Liver dysfunction:

Do not take more than 8 mg of ondansetron daily if your liver does not work properly (moderate to severe liver problems).

If you take more Setofilm® than you should

Contact your doctor, or go to the hospital immediately if you or your child have taken more Setofilm® than recommended in this package leaflet or than prescribed by your doctor. Take the medicine pack with you.

If you forget to take Setofilm®

If you forget to take Setofilm® and feel sick or vomit

- Take a dose of Setofilm® as soon as possible
- Take your next dose of Setofilm® at the usual time
- Do not take a double dose to make up for a forgotten dose

If you miss a dose but do not feel sick or vomit

- Take the next dose
- Do not take a double dose to make up for the forgotten dose

If you stop taking Setofilm®

If you feel unwell and stop taking Setofilm® tell your doctor or nurse as soon as possible.

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

4 POSSIBLE SIDE EFFECTS

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

Allergic reactions:

If you have an allergic reaction, stop taking Setofilm® and immediately contact your doctor or go to the nearest hospital. The signs of an allergic reaction may include:

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

Other side effects include:

Very common side effects (affects more than 1 in 10 people)

- Headache

Common side effects (affects less than 1 in 10 people)

- Sensation of warmth or flushing
- Constipation; tell your doctor, if you have crampy abdominal pain or difficulty in passing stools. They will need to monitor you carefully to see how the treatment is affecting you.

Uncommon side effects (affects less than 1 in 100 people)

- Hiccups
- Low blood pressure, which may make you feel faint or dizzy
- Palpitations (conscious awareness of heart beat) or irregular or slow heart beat
- Chest pain
- Fits (convulsions)
- Unusual unintentional eye or body movements or shaking
- Changes to liver function test results (changes are more common if you take ondansetron with a medicine called Cisplatin)

Rare (affects less than 1 in 1,000 people)

- Allergic reactions, sometimes severe, including anaphylaxis
- Feeling dizzy or lightheaded [when ondansetron is given intravenously (i.e. through a tube in your vein)]
- Blurred vision or temporary loss of eyesight, (predominantly when ondansetron is given intravenously) which normally comes back within 20 minutes
- Disturbance in heart rhythm and ECG changes, including a special form of heart rhythm disorder called Torsade de Pointes, (sometimes causing sudden loss of consciousness)

Very rare (affects less than 1 in 10,000 people):

- Temporary visual disturbances e.g. blurred vision (predominantly when ondansetron is given intravenously)
- A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)

Not known (frequency cannot be estimated from 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, nurse or pharmacist. 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 SETOFILM®

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Keep the sachet tightly closed in order to protect from moisture.
- Do not use Setofilm® if you notice that it is damaged.
- Medicines should not be disposed of 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 Setofilm® contains

The active substance is ondansetron. Each orodispersible film contains 4 mg or 8 mg of ondansetron (as base).

The other ingredients are: polyvinyl alcohol, macrogol 1000, acesulfame potassium E950, glycerol E422, titanium dioxide E171, rice starch, levomenthol and polysorbate 80 E433.

What Setofilm looks like and contents of the pack

Setofilm® 4 mg are white and rectangular (size 3 cm²) orodispersible films. Setofilm® 8 mg are white and rectangular (size 6 cm²) orodispersible films. Setofilm® is placed into sachets. Each carton contains 10 sachets.

Manufactured by LTS Lohmann Therapie-Systeme AG, Lohmannstrasse 2, D-56626, Andernach, Germany. Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

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