

Package leaflet: Information for the user

Setofilm® 4 mg, Orodispersible Films
Setofilm® 8 mg, Orodispersible Films
Ondansetron

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. Do not pass it on to others. It may harm them, even if their symptoms 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 (hypersensitive) to ondansetron or any of the other ingredients of Setofilm listed in section 6,
if you are allergic (hypersensitive) 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

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

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 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)
- 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 Setofilm.

SETOFILM with food and drink

You may take Setofilm with food and drink.

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

It is not known if Setofilm is safe during pregnancy. You should only use Setofilm if your doctor has told you to.

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 Setofilm 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 40kg and above, take 4mg of Setofilm 1 hour before your operation, followed by one further dose of 4mg 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, Setofilm 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)

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store SETOFILM

Keep the sachet tightly closed in order to protect from moisture.

Do not use Setofilm after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Setofilm if you notice that it is damaged.

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 SETOFILM contains

The active substance is ondansetron. Each film contains 4 mg or 8 mg of ondansetron.

The other ingredients are: poly (vinyl 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 4 mg Orodispersible Film is placed into sachets. Each carton contains 2, 4, 6, 10, 30 or 50 sachets.

Setofilm 8 mg Orodispersible Film is placed into sachets. Each carton contains 2, 4, 6, 10, 30 or 50 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Manufacturing Authorisation Holder:

Norgine B.V.
Antonio Vivaldistraat 150,
1083 HP Amsterdam,
The Netherlands

Manufacturer:

LTS Lohmann Therapie-Systeme AG
Lohmannstrasse 2
D-56626 Andernach
GERMANY

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

Setofilm: France, Ireland, UK, Belgium, Luxemburg, Portugal, Spain, Sweden, Finland, Denmark, Netherlands, Italy, Germany

Setofim: Norway

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This leaflet was last revised in 11/2018