

Package leaflet: Information for the user

/.../ 25 mg film-coated tablets

Exemestane

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 /.../ is and what it is used for
2. What do you need to know before you take /.../
3. How to take /.../
4. Possible side effects
5. How to store /.../
6. Contents of the pack and further information

1. What /.../ is and what it is used for

/.../ belongs to a group of medicines known as aromatase inhibitors. These drugs interfere with a substance called aromatase, which is needed to make the female sex hormones, oestrogens, especially in postmenopausal women. Reduction in oestrogen levels in the body is a way of treating hormone dependent breast cancer.

/.../ is used to treat:

- hormone dependent **early breast cancer** in postmenopausal women after they have completed 2-3 years of treatment with the medicine tamoxifen.
- hormone dependent **advanced breast cancer** in postmenopausal women when a different hormonal drug treatment has not worked well enough.

2. What do you need to know before you take /.../

Do not take /.../:

- if you are **allergic** to exemestane or any of the other ingredients of this medicine (listed in section 6).
- if you are **still having your monthly period**, i.e. if you have not gone through the menopause.
- if you are **pregnant or likely to be pregnant**.
- if you are **breastfeeding**.

Warnings and precautions

Talk to your doctor or pharmacist before taking /.../

- if it is not entirely clear whether you have actually reached the **menopause**. In this case your hormonal status should be tested **before** taking this medicine.
- if you have problems with your **liver or kidneys**. If this applies to you, **tell your doctor before** taking this medicine.
- if you have a **history of osteoporosis** (thinning or wasting of bones) or bone fractures. If this applies to you, **tell your doctor**. Your doctor may want to measure your bone density before and during treatment of /.../.
- if you have **Vitamin D deficiency**. If your doctor measured a low level of Vitamin D in your blood you should receive supplementation.

Other medicines and /.../

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

/.../ should not be given at the same time as hormone replacement therapy (HRT).

The following medicines should be used cautiously when taking /.../:

Tell your doctor if you are taking medicines such as:

- rifampicin (an antibiotic).
- carbamazepine or phenytoin (anticonvulsants used to treat epilepsy).
- the herbal remedy St. Johns Wort (*Hypericum perforatum*), or preparations containing St. Johns Wort.

Pregnancy and breast-feeding

Do not take /.../ if you are pregnant or breast-feeding.

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

Discuss contraception with your doctor if there is any possibility that you may become pregnant.

Driving and using machines

If you feel drowsy, dizzy or weak do not drive or operate any tools or machines.

3. How to take /.../

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

Dosage

The usual dose is one 25 mg film-coated tablet daily.

Try to take your tablet at the same time each day.

Children and adolescents

/.../ is not suitable for use in children and adolescents.

How to take /.../

Swallow the tablet whole with a glass of water after a meal.

If you take more /.../ than you should

Contact your doctor or the nearest hospital if you have taken more than the normal dose.

Take your medicine with you.

If you forget to take /.../

Do not take a double dose to make up for a forgotten tablet.

If you have forgotten to take your tablet, take it as soon as you remember. If it is nearly time for the next dose, skip the one you missed. Take the next dose at the usual time.

If you stop taking /.../

Continue taking /.../ every day for as long as your doctor tells you.

Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

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

4. Possible side effects

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

In general, /.../ is well tolerated and the following side effects observed in patients treated with /.../ are mainly

mild or moderate in nature. Most of the side effects are associated with a shortage of oestrogen (e.g. hot flushes).

Hypersensitivity, inflammation of the liver (hepatitis) and inflammation of the bile ducts of the liver which cause yellowing of the skin (cholestatic hepatitis) may occur. Symptoms include feeling generally unwell, nausea, jaundice (yellowing of the skin and eyes), itching, right sided abdominal pain and loss of appetite. Contact your doctor promptly to seek urgent medical advice if you think you have any of these symptoms.

Very common side effects (affecting more than 1 of 10 patients treated):

- Depression
- Difficulty sleeping
- Headache
- Hot flushes
- Dizziness
- Feeling sick
- Increased sweating
- Muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- Tiredness
- A reduction in the number of white blood cells
- Abdominal pain
- Elevated level of liver enzymes
- Elevated level of a hemoglobin breakdown in the blood
- Elevated level of a blood enzyme in the blood due to liver damage
- Pain

Common side effects (affecting 1 to 10 of 100 patients treated):

- Loss of appetite
- Carpal tunnel syndrome (a combination of pins and needles, numbness and pain affecting all of the hand except the little finger) or tingling/prickling of the skin
- Stomach ache, vomiting (being sick), constipation, indigestion, diarrhoea
- Hair loss
- Skin rash, hives and itchiness
- Thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- Pain, swollen hands and feet
- A reduction in the number of platelets in the blood
- Muscle weakness

Uncommon side effects (affecting 1 to 10 of 1.000 patients treated):

- Hypersensitivity

Rare side effects (affecting 1 to 10 of 10.000 patients treated)

- A breakout of small blisters on an area of the skin in a rash
- Drowsiness
- Inflammation of the liver
- Inflammation of the bile ducts of the liver which cause yellowing of the skin

Side effects with unknown frequency (cannot be estimated from the available data)

- Low level of certain white blood cells in the blood

Changes in the amount of certain blood cells (lymphocytes) and platelets circulating in your blood, especially in patients with a pre-existing lymphopenia (reduced lymphocytes in the blood) may also be seen.

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 via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../

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

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

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and further information

What /.../ contains

The active substance is exemestane. Each film-coated tablet contains 25 mg of exemestane.

The other ingredients are

- Tablet core:
Mannitol; Crospovidone; Hypromellose; Sodium starch glycolat (type A); Polysorbate 80; Cellulose, microcrystalline; Magnesium stearate; Silicia, colloidal, anhydrous
- Tablet coat:
Hyomellose, Titanium dioxide (E171), Macrogol 400

What /.../ looks like and contents of the pack

/.../ is a round, white to off-white film-coated tablet marked with an E on one side.

Pack sizes:

30, 60, 100 tablets

Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Netherlands Exemestaan Devatis 25 mg

Germany Exemestan Devatis 25 mg

This leaflet was revised in 04/2016