

The dispensing of this medicine requires a doctor's prescription

Exemasin-Vit 25 mg Coated tablets

Active ingredient and its quantity: Each coated tablet contains: Exemestane 25 mg

For inactive ingredients see Section 6.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is intended for women over 18 years old.

1. What is this medicine intended for?

Treatment of breast cancer in postmenopausal women.

Therapeutic group:

Steroidal aromatase inhibitors.

2. Before using this medicine

❑ Do not use this medicine if you:

- Are sensitive (allergic) to the active ingredient (exemestane) or to any of the other ingredients that this medicine contains. For additional information see Section 6.
- Are pregnant, likely to be pregnant or breast-feeding.
- Have not already been through the menopause, i.e. you are still having your monthly period.

❑ Special warnings about using this medicine

Before using Exemasin-Vit tell your doctor if:

- You have problems with your liver or kidney.
- You have a history or are suffering from any condition which affects the strength of your bones. Your doctor may want to measure your bone density before and during the treatment of **Exemasin-Vit**. This is because drugs of this class lower the levels of female hormones and this may lead to a loss of the mineral content of bones, which might decrease their strength.
- **Tests to be performed before using the medicine:**
 - Your doctor may want to take blood samples to make sure you have reached the menopause.
 - Routine checking of your vitamin D level. Your level may be very low in the early stages of breast cancer. You will be given vitamin D supplement by your doctor if your levels are below normal.

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular if you are taking:

- Medicines containing oestrogen
- Rifampicin (an antibiotic)
- Phenytoin or carbamazepine (anticonvulsants used to treat epilepsy)
- Herbal remedies containing hypericum (St John's Wort)

Exemasin-Vit should not be taken at the same time as hormone replacement therapy (HRT).

Using the medicine and food

Swallow the medicine after a meal.

Pregnancy and breastfeeding

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

If you are pregnant or think you might be pregnant, tell your doctor.

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 whilst taking Exemasin-Vit, you should not drive or operate machinery.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine your dose and how you should take the medicine. The recommended dose is usually:

One 25 mg tablet should be taken by mouth once a day at approximately the same time. Your doctor will determine the duration of treatment.

Do not exceed the recommended dose.

- Do not chew!
- Swallow the medicine with some water.
- If you need to go to the hospital whilst taking **Exemasin-Vit**, let the medical staff know what medication you are taking.

If you have accidentally taken a higher dose or if you have taken an overdose, or if a child has accidentally swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose to make up for a forgotten dose. Take the tablet as soon as you remember. If it is nearly time for the next dose, take the tablet at the usual time.

Persist with the treatment as recommended by the doctor.

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

- Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or the pharmacist.

4. Side effects

Like all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects. You may not suffer from any of them. In general, Exemasin-Vit is well tolerated and the following side effects observed in patients treated with Exemasin-Vit are mainly mild or moderate in nature. Most of the side effects are associated with a shortage of oestrogen (e.g. hot flushes).

Contact your doctor promptly if you suffer from:

Hypersensitivity, inflammation of the liver (hepatitis) and inflammation of the bile ducts of the liver which cause yellowing of the skin. Symptoms include feeling generally unwell, nausea, jaundice (yellowing of the skin and eyes), itching, right sided abdominal pain and loss of appetite.

Additional side effects:

Very common side effects (may affect more than 1 in 10 users):

- 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 (may affect up to 1 in 10 users):

- 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, constipation, indigestion, diarrhoea • Hair loss • Rash, hives and itchiness
- Thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures in some cases • Pain, swollen hands and feet
- A reduction in the number of platelets in the blood • Muscle weakness

Uncommon side effects (may affect up to 1 in 100 users):

- Hypersensitivity

Rare side effects (may affect up to 1 in 1,000 users):

- 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 of unknown frequency (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.

If you experience any side-effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- **Prevent poisoning!** To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not discard the medicine via wastewater or household waste. Ask the pharmacist how to dispose medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient this medicine also contains:

Silica colloidal anhydrous, crospovidone (Type A), hypromellose 5cP, mannitol, microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate and polysorbate 80.

Tablet coat contains: Opadry white OYS 9622 (hypromellose 5cP, propylene glycol and titanium dioxide).

What the medicine looks like and what are the contents of the package:

white, round, biconvex, with the E letter imprinted on one side.

The medicine is available in blister packs. Each blister pack contains 30 coated tablets.

Registration holder: Vitamed pharmaceutical industries LTD, Hatahana 6, P.B.O 114 Binyamina 3055002.

Manufacturer: Genepharm S.A, Pallini, Greece.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 156 62 34456 00

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