

**Patient leaflet in accordance with the Pharmacists'
Regulations (Preparations) - 1986**

This medicine can be sold with a physician's prescription
only

Exemasin-Vit, 25 mg, Coated tablets

The active ingredient and its quantity:

Each coated tablet contains: exemestane 25 mg.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, refer to the 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 not intended for children.

1. What is the medicine intended for?

Exemasin-Vit 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. Additionally, **Exemasin-Vit** is used for the treatment of hormone dependent advanced breast cancer in women in postmenopausal status (natural or induced), whose disease has progressed following a single hormonal (anti-estrogen) therapy or several hormonal therapies.

Therapeutic group: Steroidal inhibitors of the enzyme aromatase, anti-neoplastic (anti-cancer) agents.

Exemasin-Vit belongs to a group of medicines known as aromatase inhibitors; aromatase is an enzyme required for the production of the female sex hormones - estrogens, especially in postmenopausal women. Reduction in estrogen levels in the body is a way of treating hormone dependent breast cancer.

2. Before using this medicine

Do not use this medicine if you:

- Are or have previously been hypersensitive (allergic) to the active ingredient (exemestane) or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- Are pregnant, likely to be pregnant or breastfeeding.
- Are before menopause (you still have your monthly period).

Special warnings about using this medicine

Before using Exemasin-Vit tell the doctor if:

- You have liver or kidney problems
- You are suffering or have suffered in the past from a condition which affects the strength of your bones. Your doctor may want to perform bone mineral density tests before and during treatment with **Exemasin-Vit**. This is because this class of medicines lowers the levels of female sex hormones, which may lead to a loss of the mineral content of bones, which might decrease their strength.

Tests and follow up

Tests to be performed before using the medicine:

- Your doctor may take blood samples from you to ensure you have reached menopause.
- Routine checking of vitamin D level. In the early stages of breast cancer, your vitamin D level may be very low. The doctor will give you a vitamin D supplement if your vitamin D level is below normal.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Medicines containing estrogen
- Rifampicin (an antibiotic)
- Phenytoin or Carbamazepine (anticonvulsants used to treat epilepsy)
- Herbal preparations containing Hypericum (St. John's Wort)

Exemasin-Vit should not be taken at the same time with 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 breastfeeding.

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

If there is any possibility that you may become pregnant, consult with the doctor regarding contraception.

Driving and using machines:

If you feel drowsy, dizzy or weak while taking **Exemasin-Vit**, you must not drive or operate machines.

Important information about some of the ingredients of this medicine

This medicine contains less than 1 millimole of sodium (23 mg) per tablet, i.e. it is essentially "sodium free".

3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and the manner of treatment will be determined by the doctor only.

The recommended dose is usually:

One 25 mg tablet daily taken orally, at approximately the same time each day. Your doctor will determine the duration of treatment.

Do not exceed the recommended dose.

- There is no information regarding crushing/ splitting/ chewing **Exemasin-Vit** tablets.
- Swallow the medicine with a little water.
- If you need to go to the hospital while taking **Exemasin-Vit**, inform the medical staff about the medicines 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 the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the designated 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.

Adhere to the treatment as recommended by the doctor.

Do not stop taking the medicine even if you feel well, unless instructed to do so by the doctor.

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 further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like with any medicine, the use of **Exemasin-Vit** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Contact the doctor immediately 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.

Generally, **Exemasin-Vit** is well tolerated and the following side effects observed in patients treated with **Exemasin-Vit** are mainly mild or moderate. Most of the side effects are associated with a shortage of estrogen (such as hot flushes).

Additional side effects:

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

- Depression
- Difficulty falling asleep
- Headache
- Hot flushes
- Dizziness
- Nausea
- 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
- High level of alkaline phosphatase enzyme in the blood due to liver damage
- Pain

Common side effects (may affect up to 1 in 10 users):

- Lack of appetite
- Carpal tunnel syndrome (a combination of "pins and needles", numbness and pain affecting all of the hand except the little finger) or pricking or tingling of the skin
- Vomiting, constipation, indigestion, diarrhea
- Hair loss
- Skin rash, hives and itchiness
- Bone depletion which might decrease their strength (osteoporosis), leading in some cases to bone fractures (breaks or cracks)
- Swollen hands and feet
- A reduction in blood platelet count
- Feeling of 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 in a certain area of the skin in a rash
- Drowsiness
- Inflammation of the liver
- Inflammation of the bile ducts of the liver which causes yellowing of the skin

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Low level of certain white blood cells in the blood

It is possible that there may be changes in the level of certain blood cells (lymphocytes) and platelets in the bloodstream, especially in patients with a pre-existing lymphopenia (low level of lymphocytes in the blood).

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medical treatment" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away 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:

Microcrystalline Cellulose, Mannitol, Crospovidone (Type A), Sodium Starch Glycolate (Type A), Hypromellose 5cP, Polysorbate 80, Silica Colloidal Anhydrous, Magnesium Stearate.

Tablet coat contains: Opadry OYS 9622,

(consists of: Hypromellose 5cP, Titanium Dioxide and Propylene Glycol).

What the medicine looks like and what the package contains:

White, round, biconvex, coated tablets, with the letter E embossed on one side.

Approved package sizes: The medicine is available in blister packages containing 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120 coated tablets.

Not all package sizes may be marketed.

Registration holder's name and address:

Vitamed Pharmaceutical Industries Ltd.,
6 Hatahana St., P.O.B. 114 Binyamina 3055002, Israel.

Manufacturer's name and address:

Genepharm S.A., 18TH KM Marathonos Avenue, 15351 Pallini, Greece.

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Registration number of the medicine in the National Drug Registry of the Ministry of

Health: 156-62-34456-00