1.3.2 Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VESOTA for solution for injection

Fulvestrant

Sugar free

Read all of this leaflet carefully before you are given VESOTA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What VESOTA is and what it is used for

VESOTA contains the active substance fulvestrant, which belongs to the group of estrogen blockers. Estrogens, a type of female sex hormones, can in some cases be involved in the growth of breast cancer.

VESOTA is used to treat postmenopausal women with a type of breast cancer called estrogen receptor positive breast cancer that is locally advanced or has spread to other parts of the body (metastatic).

2. What you need to know before you are given VESOTA

VESOTA should not be administered to you:

- If you are hypersensitive (allergic) to fulvestrant or any of the ingredients of VESOTA (listed in section 6).
- If you have severe liver problems.
- If you are pregnant or breastfeeding your baby.

VESOTA should not be given to men or children.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

•If you have any problems with your liver or kidneys.

• If you have been told you have a low blood platelet count, a bleeding disorder or if you use anticoagulants (medicine to prevent blood clots).

Special care should be taken with VESOTA:

If you have or have ever had a problem with alcoholism.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before being given this medicine.

Children and adolescents

VESOTA has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and VESOTA:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

In particular, you should tell your doctor if you are using anticoagulants (medicines to prevent blood clots).

Pregnancy, breastfeeding and fertility

Women of child-bearing potential and male/female contraception

If you can become pregnant, you should use effective contraception while you are being treated with VESOTA and for 2 years after your last dose.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

You must not be given VESOTA if you are pregnant.

You must not breastfeed your baby while on treatment with VESOTA as it may harm your baby.

Driving and using machines

VESOTA is not expected to affect your ability to drive or use machines. However, some patients may occasionally feel tired. If this happens to you, ask your doctor, pharmacist or other health care professional for advice.

It is not always possible to predict to what extent VESOTA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which VESOTA affects you.

VESOTA contains ethanol (alcohol)

VESOTA contains 500 mg of ethanol (96%) per injection, equivalent to 10 ml beer or 4 ml wine. This may be harmful for those suffering from alcoholism. This should also be taken into account if you have liver disease, or epilepsy.

VESOTA contains benzyl alcohol

VESOTA contains 500 mg benzyl alcohol per injection, equivalent to 100 mg/ml.

Benzyl alcohol may cause allergic reactions.

VESOTA contains benzyl benzoate

VESOTA contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. How to use VESOTA

Always use VESOTA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 500 mg fulvestrant (two 250 mg/5 mL injections) given once a month, with an additional 500 mg dose given two weeks after the initial dose.

Your doctor or nurse will give you VESOTA injection.

VESOTA will be slowly injected into the muscle of each of your buttocks.

Your doctor will tell you how long your treatment with VESOTA will last. Do not stop any treatment unless your doctor tells you to do so.

If you have the impression that the effect of VESOTA is too strong or too weak, tell your doctor or pharmacist.

If you are administered more VESOTA than you should

Since a health care provider will administer VESOTA , he/she will control the dosage, However, in the event of overdosage your doctor will manage the dosage.

If the dose of VESOTA is forgotten

Since a health care provider will administer VESOTA, it is unlikely that the dose will be missed.

4. Possible side effects

VESOTA can have side effects.

Not all side effects reported for VESOTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using VESOTA , please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using VESOTA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling around the eyes, face, lips and mouth or tongue, which may cause difficulty in swallowing or breathing
- Rash or itching

- Yellowing of the skin or eyes

These are all very serious side effects. If you have them, you may have had a serious reaction to VESOTA. You may need urgent medical attention or hospitalisation.

Treatment with VESOTA can very commonly cause reactions where the injection is administered, muscle weakness, nausea and increase in liver enzymes (seen on laboratory tests).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Injection site reactions, such as pain and/or inflammation.
- Weakness
- Nausea
- Joint and musculoskeletal pain, back pain
- Hot flushes
- Headache
- Gastro-intestinal symptoms (symptoms from the stomach or the bowels), such as, vomiting, diarrhoea or loss of appetite
- Skin rash
- Urinary tract infections (bladder infections)
- Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), liver pain or liver swelling.

- Increased level of bilirubin (yellow pigmented chemical produced by the liver), seen in blood tests.
- Decreased levels of platelets (thrombocytopenia), seen in blood tests.
- Vaginal bleeding
- Lower back pain irradiating to leg on one side (sciatica)
- Sudden weakness, numbness, tingling, or loss of movement in your leg, especially on only one side of your body, sudden problems with walking or balance (peripheral neuropathy)

Less frequent side effects:

- Increased levels of enzymes produced in the liver (called AST, ALT, ALP, and Gamma GT)
- Thick, whitish vaginal discharge and candidiasis (infection)
- Bruising and bleeding at the site of injection
- Inflammation of the liver (hepatitis)
- Liver failure
- Numbness, tingling and pain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VESOTA.

5. How to store VESOTA

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

VESOTA will be stored in the pharmacy.

Store at or below 5 °C.

Keep the container in the outer carton in order to protect from light.

Do not use after the expiry date stated on the vial and the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What VESOTA contains

The active substance is fulvestrant.

Each pre-filled syringe contains 250 mg of fulvestrant.

The other ingredients of VESOTA are ethanol (96 %), benzyl alcohol, benzyl benzoate and castor oil.

What VESOTA looks like and contents of the pack

VESOTA is a clear, colourless to yellow viscous solution, essentially free from visible particle, in a 5 mL clear glass barrel with a cap and a grey plunger stopper with a transparent plunger rod. VESOTA comes in a container with 2 syringes that are filled and ready for injection together with 2 safety needles.

HOLDER OF CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

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