

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### FUVISTRA

(Fulvestrant 250 mg/5ml Solution for injection)

Ethanol (96 %): 10 % *m/v*

Benzyl Alcohol: 10 % *m/v*

Benzyl Benzoate: 150mg/ml (750mg per injection)

(Sugar free)

### Read all of this leaflet carefully before you start using FUVISTRA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **FUVISTRA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

1. What **FUVISTRA** is and what it is used for
2. What you need to know before you use **FUVISTRA**
3. How to use **FUVISTRA**
4. Possible side effects
5. How to store **FUVISTRA**
6. Contents of the pack and other information

### 1. WHAT FUVISTRA IS AND WHAT IT IS USED FOR

**FUVISTRA** contains an active substance called fulvestrant, which belongs to the group of estrogen blockers. Estrogens, a type of female sex hormones.

**FUVISTRA** is used to treat breast cancer in postmenopausal women.

**FUVISTRA** is a medicine that stops some of the actions of estrogen (female sex hormone) within the body, which has an effect on the growth of breast cancer.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE FUVISTRA**

### **Do not use FUVISTRA:**

- If you are allergic to **FUVISTRA** or any of the other ingredients of **FUVISTRA**
- If you have severe liver problems.
- If you are pregnant or breastfeeding an infants
- **FUVISTRA** should not be given to children or men.

If you are not sure, talk to your doctor or pharmacist before taking **FUVISTRA**.

### **Warnings and precautions**

#### **Take special care with FUVISTRA:**

Tell your doctor or health care provider 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).
- If you have advanced breast cancer.
- If you suffer with lower back pain irradiating to leg on one side (sciatica).
- If you suffer with sudden weakness, loss of movement in your leg, especially on only one side of the body, problems with walking or balance, tingling, numbness (feeling of pins and needles) usually in the hands and feet.
- If you have osteoporosis (thinning of your bones).

- If you suffer with narrowing of blood vessels to certain organs.
- If you are also taking the medicine, palbociclib.

### **Hypersensitivity (allergic) reactions:**

Hypersensitivity (allergy), including swelling of the face, lips, tongue and/or throat (angioedema) and itchy rash, weals and swelling of the skin (urticaria) has been commonly reported and can be serious. If you have any of these symptoms, you may have had a serious allergic reaction to **FUVISTRA** and may need urgent medical attention or hospitalisation.

### **Children and adolescents**

**FUVISTRA** is not indicated in children and adolescents under 18 years

### **Other medicines and FUVISTRA**

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines), the use of **FUVISTRA** with these medicines may cause undesirable Interactions.

When fulvestrant is combined with palbociclib, please also refer to the Professional Information of palbociclib.

Due to the structural similarity of fulvestrant and estradiol, fulvestrant may interfere with antibody based-estradiol assays and may result in falsely increased levels of estradiol.

### **Pregnancy, breastfeeding and fertility**

You must not use **FUVISTRA** if you are pregnant. If you can become pregnant, you should use effective contraception while you are being treated with **FUVISTRA** and for 2 years after your last dose.

You must not breast-feed while on treatment with **FUVISTRA**.

### **Driving and using machines**

**FUVISTRA** 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.

**FUVISTRA** contains 10 % w/v ethanol (alcohol), i.e. up to 500 mg per injection, equivalent to 10 ml beer or 4 ml wine.

To be taken into account in high-risk groups such as patients with liver disease, or epilepsy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

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

Ask your doctor or pharmacist for advice if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

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

### **3. HOW TO USE FUVISTRA**

Do not share medicines prescribed for you with any other person.

Your doctor or nurse will give you the **FUVISTRA** injection.

The usual dose is 2 injections given once a month, with an additional 2 injections given two weeks after the initial dose, but your doctor decides the exact dose.

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

#### **If you have been given more FUVISTRA than you should**

If you are given too much **FUVISTRA**, Your doctor will know how to treat you based on your condition.

#### **4. POSSIBLE SIDE EFFECTS**

**FUVISTRA** can have side effects.

Not all side effects reported for **FUVISTRA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **FUVISTRA**, please consult your health care provider for advice.

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

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- Allergic reactions (Hypersensitivity reactions)
- Allergic reactions, including swelling of the face, lips, tongue and/or throat that may be signs of anaphylactic reactions.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Increased risk of blood clots (Thromboembolism)
- Nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (Hepatitis)
- Hepatic failure
- Injection site haemorrhage, injection site haematoma

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent:*

- Fever or high temperature (Pyrexia)
- loss of appetite (Anorexia)s
- Headache
- Feeling sick (Nausea)
- Being sick (Vomiting)
- Loose stool (Diarrhoea)
- Urinary tract infections
- Reduced platelet count
- Hot flushes
- Increase of bilirubin (bile pigment produced by the liver)
- Elevated liver enzymes (ALT, AST, ALP)
- Back pain

- Joint and musculoskeletal pain
- Lower back pain irradiating to leg on one side (sciatica)
- Vaginal bleeding
- Thick, whitish vaginal discharge and candidiasis (leukorrhea)
- Itching, burning and a thick, white, “cottage cheese” discharge (Vaginal moniliasis)
- Injection site reactions
- Unusual weakness (asthenia)
- 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:

- Elevated gamma-GT
- Severe stabbing or throbbing pain along one or more nerves (neuralgia)

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **FUVISTRA**.

### **5. HOW TO STORE FUVISTRA**

- Store all medicines out of reach of children.
- Store between 2 °C and 8 °C (in a refrigerator). Do not freeze.
- Keep the pre-filled syringe in the original package, in order to protect from light.

- Do not use after the expiry date stated on the label / carton / syringe.
- Your healthcare professional will be responsible for the correct storage, use and disposal of **FUVISTRA**.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What FUVISTRA contains**

Each pre-filled syringe contains 250 mg/5 ml (5 % *m/v*) Fulvestrant.

The other ingredients are: Ethanol 96 % (alcohol) (Emprove), Benzyl alcohol (Parenteral Grade), Benzyl Benzoate, Castor oil Refined, Nitrogen.

### **What FUVISTRA looks like and the contents of the pack**

Clear colourless to yellow viscous solution, free from visible particles, filled in 5ml Pre-filled syringe.

2 x 5 ml pre-filled syringes packed in a lidded tray with two needles in a printed carton.

## **HOLDER OF CERTIFICATE OF REGISTRATION AND MANUFACTURER**

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