PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

FULVEDEX 250 mg/5 ml injection

Fulvestrant

Sugar free

Read all of this leaflet carefully before you start using FULVEDEX

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

What is in this leaflet

1. What FULVEDEX is and what it is used for

FULVEDEX contains a medicine called fulvestrant which belongs to a class of medicines called hormone inhibitors. It blocks oestrogen, a type of female sex hormone, which can in some cases be involved in the growth of breast cancer.

FULVEDEX is used to treat:

- Breast cancer in postmenopausal women.

2. What you need to know before you use FULVEDEX

Do not use FULVEDEX:

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

Warnings and precautions

Talk to your doctor before using FULVEDEX. Special care should be taken with FULVEDEX:

- 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 suffer from a loss of bone density (osteoporosis).

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 FULVEDEX and may need urgent medical attention or hospitalisation.

Children and adolescents

FULVEDEX is not recommended for use in children and adolescents.

Other medicines and FULVEDEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

FULVEDEX should not be given with oestradiol (female sex hormone), as it may result in falsely increased levels of oestradiol.

FULVEDEX with alcohol

FULVEDEX contains ethanol (alcohol) 500 mg (10 % *w/v*) per injection. This may be harmful if you suffer from alcoholism, liver disease or epilepsy.

FULVEDEX contains benzyl alcohol

Benzyl alcohol may cause an allergic reaction.

Pregnancy and breastfeeding

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 health care provider for advice.

Do not use FULVEDEX if you are pregnant or during breastfeeding.

If there is a possibility that you could become pregnant, then you should use an effective contraception during treatment with FULVEDEX and for 2 years after the last dose.

Driving and using machines

FULVEDEX 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.

3. How to use FULVEDEX

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

Always use FULVEDEX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will not be expected to give yourself FULVEDEX. It will be given to you by a person who is qualified to do so.

Your doctor or nurse will give you the FULVEDEX 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 will decide the exact dose.

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

Your doctor will tell you how long your treatment with FULVEDEX will last. If you have the impression that the effect of FULVEDEX is too strong or too weak, tell your doctor or pharmacist.

If you receive more FULVEDEX than you should

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

If you forget to use FULVEDEX

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

4. Possible side effects

FULVEDEX can have side effects.

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

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

- Hypersensitivity (allergy) which include swelling of the face, lips, tongue and/or throat (angioedema) and itchy rash, weals and swelling of the skin (urticaria).

These are all very serious side effects. If you have them, you may have had a serious reaction to FULVEDEX. 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:

- Blood clots (venous thromboembolism)
- Liver failure
- Inflammation of the liver (hepatitis)

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

Tell your doctor if you notice any of the following:

Frequent

- Urinary tract infections (bladder infection)
- Reduced platelet count
- Skin rash (urticaria)
- Anorexia

- Headache
- Hot flushes
- Nausea (feeling sick), vomiting (being sick) and diarrhoea
- Abnormal levels of liver enzymes (in blood tests)
- Back, joint and musculoskeletal pain
- Vaginal bleeding
- Injection site reactions, such as pain and/or inflammation
- 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

- Anaphylactic reaction
- Increase of gamma-GT, a liver enzyme seen in a blood test
- Thick, whitish vaginal discharge and candidiasis (infection)
- Bruising and bleeding at the site of injection
- 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. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions 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 FULVEDEX.

5. How to store FULVEDEX

Store all medicines out of reach of children.

- Store between 2 °C to 8 °C (in a refrigerator)
- Do not freeze
- Store in the original package/ container until required for use
- Protect from light
- Do not use after the expiry date stated on the label / carton / bottle

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 FULVEDEX contains

- The active substance is fulvestrant.
- The other ingredients are ethanol 96 % 500 mg/ 5ml (10 % *m/v*), benzyl alcohol 500 mg/5 ml (10 % *m/v*), benzyl benzoate, castor oil and nitrogen (E941).

What FULVEDEX looks like and contents of the pack

FULVEDEX is a clear, colourless to yellow, viscous liquid.

The pre-filled syringe presentation consists of 2 x 5 ml colourless, transparent pre-filled syringe barrels made of borosilicate glass (Type I), with a luer tip and a tip cap. It contains a grey fluoropolymer coated bromobutyl rubber plunger (5 ml). The two (2) syringes are presented in a tray with a plunger rod and fitted with a backstop. Two (2) safety needles (SafetyGlide) for connection to each barrel are also provided.

All of the above is kept in a carton to prevent light exposure.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

106, 16th Road

Midrand

1686

South Africa

This leaflet was last revised in

8 November 2022

Application number

550531

Access to the corresponding Professional Information

To be confirmed