SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Faslodex® 250 mg/5 ml Injection (fulvestrant 250 mg/5 ml per pre-filled syringe)

Read all of this leaflet carefully before you start using FASLODEX.

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

1. WHAT FASLODEX CONTAINS:

FASLODEX comes in a container with a syringe that is filled and ready for injection. Each syringe contains 250 mg of fulvestrant.

The other ingredients are benzyl alcohol, benzyl benzoate, castor oil and ethanol (10 % m/v).

2. WHAT FASLODEX IS USED FOR:

FASLODEX is used to treat breast cancer in postmenopausal women.

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

3. BEFORE YOU RECEIVE FASLODEX:

Do not receive FASLODEX:

- If you are hypersensitive (allergic) to fulvestrant or any of the other ingredients of FASLODEX.
- If you have severe liver problems.

- If you are pregnant or breastfeeding an infant
- FASLODEX should not be given to children or men.

Take special care with FASLODEX:

Before receiving FASLODEX tell your doctor, pharmacist or other health care professional:

- 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).

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 FASLODEX and may need urgent medical attention or hospitalisation.

Pregnancy and breastfeeding:

- Do not receive FASLODEX if you are pregnant or breastfeeding an infant.
- If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or health care professional for advice.

Driving and using machinery:

FASLODEX 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.

Taking other medicines with FASLODEX:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of FASLODEX with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

4. HOW TO RECEIVE FASLODEX:

Your doctor or nurse will give you the FASLODEX 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.

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

5. POSSIBLE SIDE EFFECTS:

FASLODEX can have side effects.

Not all side effects reported for FASLODEX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking FASLODEX, please consult your doctor, pharmacist or other health care professional for advice.

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

- Hypersensitivity is a common side effect, and can be serious.
- Hypersensitivity (allergy) can include swelling of the face, lips, tongue and/or throat (angioedema) and itchy rash, weals and swelling of the skin (urticaria).

If you have any of these symptoms, you may have had a serious allergic reaction to FASLODEX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you experience any of the following side effects:

Frequent:

- Injection site reactions, such as pain and/or inflammation.
- Weakness
- Nausea
- Joint and musculoskeletal 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.

The following side effects can also occur with FASLODEX, and they are seen when a blood test is taken:

Frequent:

- Increased level of bilirubin (yellow pigmented chemical produced by the liver).
- Decreased levels of platelets (thrombocytopenia).

Less frequent:

- Increased levels of enzymes produced in the liver (called AST, ALT, ALP, and Gamma GT).

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

6. STORING AND DISPOSING OF FASLODEX:

The injections will normally be stored for you by your doctor or the hospital. The staff are responsible for the correct storage, use and disposal of FASLODEX.

Store between 2 °C and 8 °C (in a refrigerator). Do not freeze.

Keep the injections in the original pack and do not break the seal, in order to protect from light.

The injections should not be used after the expiry date on the pack.

Store all medicines out of reach of children.

7. PRESENTATION OF FASLODEX:

FASLODEX comes in a container with 2 syringes that are filled and ready for injection together with 2 safety needles.

8. IDENTIFICATION OF FASLODEX:

Thick, clear, colourless to yellow liquid.

9. REGISTRATION NUMBER:

A38/21.12/0656

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West

Bryanston, Johannesburg

2191

11. DATE OF PUBLICATION:

Date on the registration certificate of the medicine

17 February 2006

Date of the most recently revised patient information leaflet as approved by Council

7 June 2019

AstraZeneca Logo

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