PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

FASLODEX® 250 mg solution for injection
Fulvestrant
Sugar free

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, pharmacist, nurse or other health care provider
- 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.

What is in this leaflet

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

1. What FASLODEX is and what it 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.

2. What you need to know before you use FASLODEX

Do not use FASLODEX

- If you are hypersensitive (allergic) to fulvestrant or any of the other ingredients of FASLODEX (listed in section 6).
- If you have severe liver problems.
- If you are pregnant or breastfeeding an infant
- FASLODEX should not be given to children or men.

Warnings and precautions

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 osteoporosis (loss of bone density)

- If you have ever been dependent on alcohol

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.
  FASLODEX contains alcohol which may cause allergic reactions.

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

Pregnancy and breastfeeding
- Do not receive FASLODEX if you are pregnant or breastfeeding **[**~~an~~**]** your infant.
- If you can become pregnant, you should use effective contraception while you are being treated with FASLODEX and for 2 years after your last dose
- 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 machines
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.

FASLODEX contains
FASLODEX contains 10% w/v ethanol (alcohol), i.e. up to 500 mg per Injection.
FASLODEX contains 500 mg benzyl alcohol per injection, equivalent to 100 mg/ml.
FASLODEX contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. How to use 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.

If you take more FASLODEX than you should
Since a health care provider will administer FASLODEX, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. 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 health care provider 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) with difficult breathing 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.

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 FASLODEX.

5. How to store 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.

6. Contents of the pack and other information

What FASLODEX contains

The active substance is fulvestrant. Each syringe contains 250 mg of fulvestrant.
The other ingredients are benzyl alcohol, benzyl benzoate, refined castor oil and ethanol (10 % m/v).

What FASLODEX looks like and contents of the pack

Thick, clear, colourless to yellow liquid.
FASLODEX comes in a container with 2 syringes that are filled and ready for injection together with 2 safety needles.

Holder of certificate of registration

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