SCHEDULING STATUS:

S4

FULVESTRANT MYLAN 250 mg solution for injection

Fulvestrant 250 mg/ 5 ml

Read all of this leaflet carefully before you start using FULVESTRANT MYLAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FULVESTRANT MYLAN 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 FULVESTRANT MYLAN is and what it is used for.
2. What you need to know before you use FULVESTRANT MYLAN.
3. How to use FULVESTRANT MYLAN.
4. Possible side effects.
5. How to store FULVESTRANT MYLAN.
6. Contents of the pack and other information.

1. What FULVESTRANT MYLAN is and what it is used for

FULVESTRANT MYLAN is used to treat **advanced** breast cancer in postmenopausal women.

FULVESTRANT MYLAN 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 FULVESTRANT MYLAN

You should not receive FULVESTRANT MYLAN:

- if you are allergic (hypersensitive) to fulvestrant or any other ingredients of FULVESTRANT MYLAN (listed in section 6).
- if you have serious liver disorders.
- if you are pregnant or breastfeeding.

Children and adolescents

FULVESTRANT MYLAN should not be given to children and adolescents younger than 18 years.

Warnings and precautions

Before FULVESTRANT MYLAN is given to you, tell your doctor or healthcare provider.

Special care should be taken with FULVESTRANT MYLAN:

- if you have liver problems.
- if you have kidney problems.
- if you have low numbers of platelets (which help blood clotting) or bleeding disorders; previous problems with blood clots.
- if you have osteoporosis (thinning of your bones).

- if you receive treatment with FULVESTRANT MYLAN you may develop hypersensitivity (allergic) reactions, such as itching of the skin, sudden swelling of the skin or mucous membranes (e.g. throat or tongue) with difficulty breathing and hives.
- if you suffer from alcoholism.

Other medicines and FULVESTRANT MYLAN

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

In particular, you should tell your doctor if you are using anticoagulants (medicines to prevent blood clots) as this may affect how FULVESTRANT MYLAN works.

Due to structural similarities of fulvestrant and estradiol, FULVESTRANT MYLAN can interfere with estradiol measurement by immunoassay, resulting in falsely elevated estradiol levels.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or plan to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving FULVESTRANT MYLAN.

You must not use FULVESTRANT MYLAN if you are pregnant. If you can become pregnant, you should use effective contraception while being treated with FULVESTRANT MYLAN and for two years after last dose.
You must not breastfeed while on treatment with FULVESTRANT MYLAN.

Driving and using machines

FULVESTRANT MYLAN is not expected to affect your ability to drive or use machines.

However, if you feel tired after treatment do not drive or use machines.

FULVESTRANT MYLAN contains ethanol, benzyl alcohol:

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

It may be harmful for those suffering from alcoholism.

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

FULVESTRANT MYLAN contains 500 mg benzyl alcohol per injection. Benzyl alcohol may cause allergic reactions and other side effects.

3. How to use FULVESTRANT MYLAN

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

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

Your doctor or nurse will give you FULVESTRANT MYLAN as a slow intramuscular injection (1-2 minute/injections) in each buttock.

The usual dose is 2 injections (500 mg) given once a month, with an additional 2 injections given two weeks after the initial dose, but your doctor will decide on the exact dose and how long your treatment will last. Ask your doctor or healthcare provider if you have any questions.

FULVESTRANT MYLAN is not recommended for use in children or adolescents younger than 18 years, as safety and effectiveness have not been established in this age group.

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

If you receive more FULVESTRANT MYLAN than you should:

Since a healthcare professional will administer FULVESTRANT MYLAN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of FULVESTRANT MYLAN:

Since a healthcare provider will administer FULVESTRANT MYLAN, it is unlikely that the dose will be missed.

4. Possible side effects

FULVESTRANT MYLAN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.
- throat tightness, shortness of breath and wheezing.

- rash, “hives” (raised bumps), blisters or itching.

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

- thromboembolism (increased risk of blood clots),
- inflammation of the liver (hepatitis),
- liver failure.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased levels of platelets (thrombocytopenia),
- hypersensitivity reactions (angioedema, urticaria),
- lack or loss of appetite (anorexia),
- headache,
- hot flushes, blood clots in the veins (venous thromboembolism),
- nausea (feeling sick), vomiting, diarrhoea,
- abnormal levels of liver enzymes (in blood tests), increase of bilirubin (bile pigment produced by the liver),
- skin rash,
- joint and muscle pain (e.g. arthralgia, myalgia), back pain,
- vaginal bleeding,
- weakness, tiredness, injection site reactions such as pain and/or inflammation,

- 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),
- lower back pain irradiating to leg on one side (sciatica).

Less frequent side effects:

- life-threatening allergic reaction (anaphylactic),
- liver failure, hepatitis, increase of gamma-GT,
- 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 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 FLUVESTRANT MYLAN.

5. How to store FULVESTRANT MYLAN

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.

Do not use FULVESTRANT MYLAN after the expiry date which is stated on the carton or syringe labels after the abbreviation EXP. The expiry date refers to the last day of that month.

Your healthcare professional will be responsible for the correct storage, use and disposal of FULVESTRANT MYLAN.

6. Contents of the pack and other information

What FULVESTRANT MYLAN contains

The active substance is fulvestrant.

Each pre-filled syringe contains 250 mg/5 ml (5 % m/v) fulvestrant in a long-acting formulation.

This product contains 10 % m/v ethanol (96 %).

The other ingredients are benzyl alcohol, benzyl benzoate, castor oil.

What FULVESTRANT MYLAN looks like and contents of the pack

Clear, colourless to yellow, viscous liquid, free from visible particulate matter.

FULVESTRANT MYLAN comes in a tray with 2 glass syringes that are filled and ready for injection together with 2 safety needles.

Holder of Certificate of Registration

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This leaflet was last revised in

03 July 2024

Registration number

50/21.12/1066