APPROVED PATIENT INFORMATION LEAFLET
DR. REDDY'S LABORATORIES (PTY) LTD.
ERANFU 250 (INJECTION)

SCHEDULING STATUS

S4

ERANFU 250

solution for injection

fulvestrant

Read all of this leaflet carefully before you start receiving ERANFU 250

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- ERANFU 250 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 ERANFU 250 is and what it is used for
2. What you need to know before you take ERANFU 250
3. How to take ERANFU 250
4. Possible side effects
5. How to store ERANFU 250
6. Contents of the pack and other information

1. What ERANFU 250 is and what it is used for

ERANFU 250 contains a medicine called fulvestrant.

Fulvestrant belongs to the group of oestrogen blockers. Oestrogens, a type of female sex hormone, can in some cases be involved in the growth of breast cancer.

ERANFU 250 is used to treat advanced breast cancer in postmenopausal women.

2. What you need to know before you are given ERANFU 250

You should not be administered with ERANFU 250 if you:

- are hypersensitive (allergic) to fulvestrant or any of the ingredients of ERANFU 250 (see section 6).
- have severe liver problems.
- are pregnant or breastfeeding.

Warnings and precautions

Before ERANFU 250 is given to you, tell your doctor or healthcare provider:

- if you have liver problems.
- if you have kidney problems.
- if you have low numbers of platelets (cells which help blood clotting) or bleeding disorders.
- if you suffer from osteoporosis (loss of bone density).
- if you are an alcoholic.

Children and adolescents

ERANFU 250 is not indicated in children and adolescents less than 18 years.

Other medicines and ERANFU 250

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

In particular, tell your doctor if:

- you are using anticoagulants (medicines to prevent blood clots) as this may affect how ERANFU 250 works.

ERANFU 250 with food and drink

There is no information to suggest that food and drink consumption affects the way ERANFU 250 works.

Pregnancy breastfeeding and fertility

You must not use ERANFU 250 if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ERANFU 250.

If you are a woman who can become pregnant you should use a highly effective method of contraception while using ERANFU 250 and for 2 years after stopping treatment with ERANFU 250.

ERANFU 250 may pass into breast milk and therefore you should not breastfeed your baby during treatment with ERANFU 250.

Driving and using machines

ERANFU 250 is not expected to affect your ability to drive or operate machinery. However, if you feel tired after your treatment you should not drive or operate machines.

ERANFU 250 contains 10 % w/v ethanol (alcohol), i.e. up to 500 mg per injection, equivalent to 10 ml beer or 4 ml wine.

It is harmful for those suffering from alcoholism.

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

ERANFU 250 contains 500 mg benzyl alcohol per injection, equivalent to 100 mg/ml. Benzyl alcohol may cause allergic reactions.

ERANFU 250 contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. How to use ERANFU 250

ERANFU 250 will always be prepared and given to you by a healthcare professional. It is given as a slow intramuscular injection, one in each of your buttocks.

The usual dose is 500 mg (2 injections) given once a month with an additional 500 mg dose (2 injections) given 2 weeks after the first dose.

Your doctor will decide on the dose and how long your treatment should last.

Instructions for administration

The proper method of administration of ERANFU 250 for intramuscular use is described in the following instructions:

For each single-dose prefilled syringe:

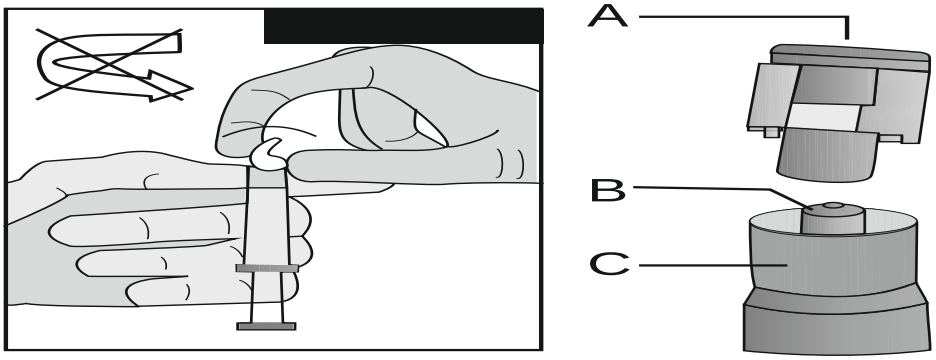
1. Remove glass syringe barrel from tray and check that it is not damaged.
2. Remove perforated patient record label from syringe.

3. Inspect the contents in the glass syringe for any visible particulate matter or discoloration prior to use. Discard if particulate matter or discoloration is present.

4. Peel open the safety needle (SurGuard® 3 Safety hypodermic needle) outer packaging.

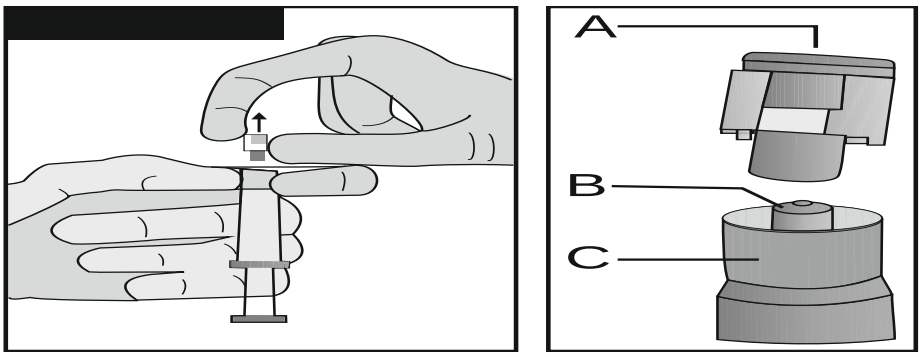
5. Hold the syringe upright on the ribbed part (C). With the other hand, take hold of the cap (A) and carefully tilt cap back and forth (DO NOT TWIST CAP) until the cap disconnects for removal (see Figure 1).

Figure 1



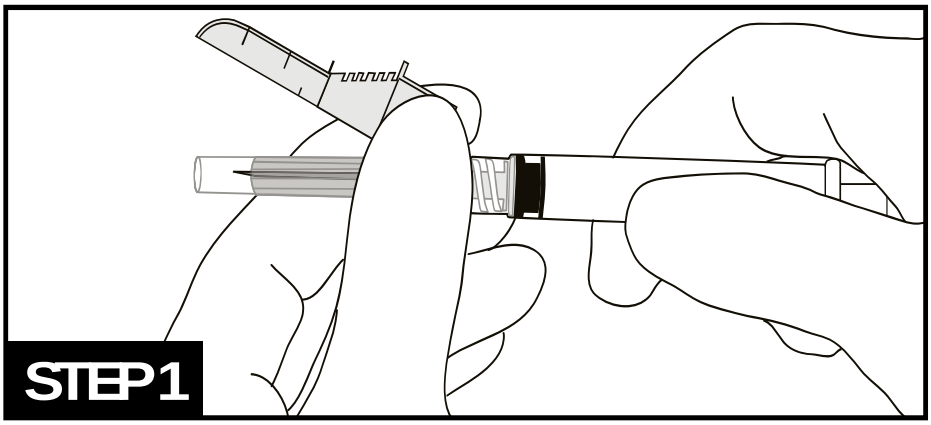
6. Pull the cap (A) off in a straight upward direction. DO NOT TOUCH THE STERILE SYRINGE TIP (Luer-Lok) (B) (see Figure 2).

Figure 2



7. Attach and tighten the syringe to the needle using aseptic technique. Grip the base of the needle, not the safety sheath, push and turn the syringe clockwise (see STEP 1).

Confirm that the needle is locked to the Luer connector before moving or tilting the syringe out of the vertical plane to avoid spillage of syringe contents.



8. Move the safety sheath away from the needle and toward the syringe barrel to the angle shown, prior to removing the needle cap.

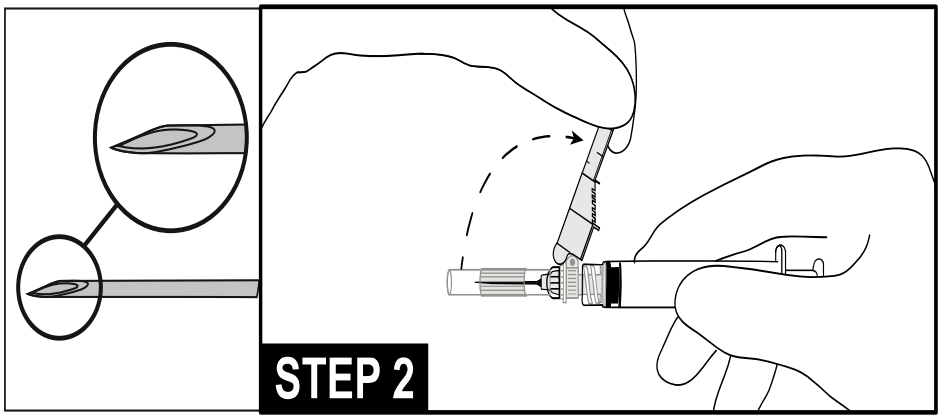
For Administration:

9. Pull shield straight off needle to avoid damaging needle point.

10. Remove needle sheath.

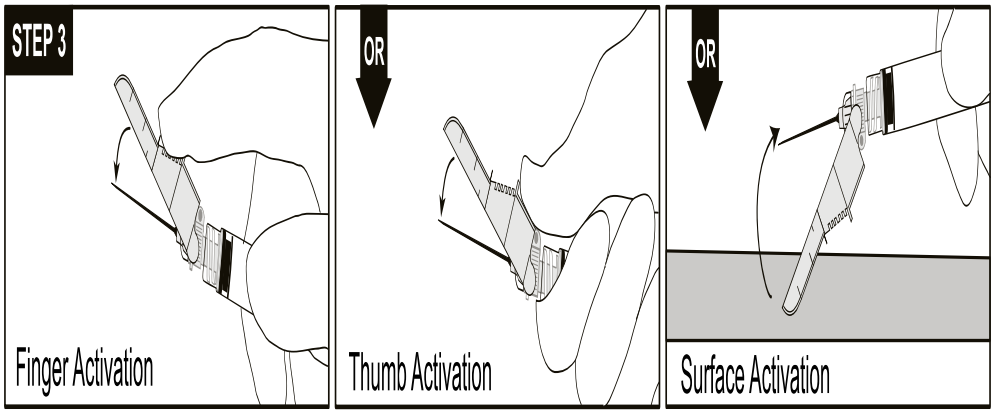
11. Expel excess air from the syringe (a small gas bubble may remain).

12. Administer intramuscularly slowly (1 to 2 minutes/injection) into the buttock (gluteal area). For user convenience, the needle "bevel up" position is oriented to the position of the safety sheath. (See STEP 2).



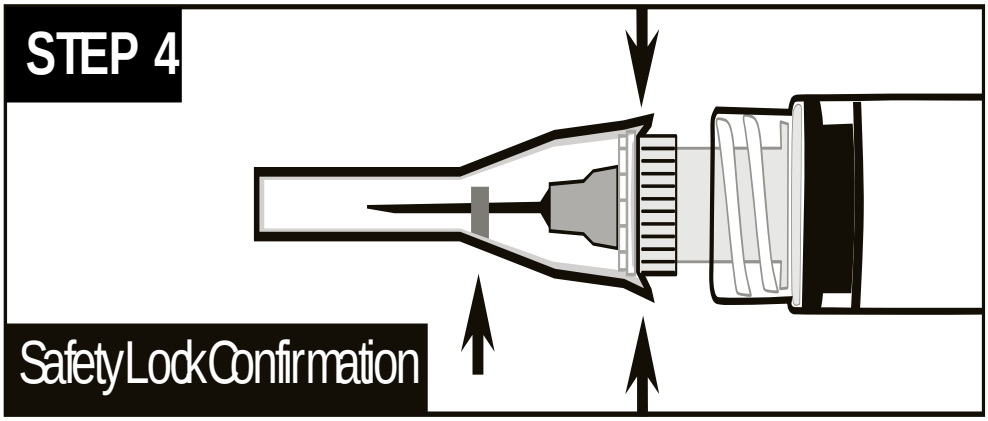
13. After the injection procedure, use a one-handed technique to activate the safety mechanism using any of the three (3) methods illustrated below.

(Activation is verified by an audible and/or tactile "click" and can be visually confirmed.) (see STEP 3).



NOTE: Activate away from self and others

14. Visually confirm that the safety sheath is fully engaged. See STEP 4.



15. Dispose of used needles and materials following the policies and procedures of your facility as well as federal and local regulations for sharps disposal.

16. Repeat steps 1 through 15 for second syringe.

If you forget to receive ERANFU 250

Since a health care provider will administer ERANFU 250, it is unlikely that the dose will be missed.

If you stop receiving ERANFU 250

Discuss the effects of stopping treatment with ERANFU 250 if you choose to do so with your doctor.

4. Possible side effects

ERANFU 250 can have side effects. Not all side effects reported for ERANFU 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ERANFU 250, 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:

- Allergic reactions including swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck 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 experience these, you may have had a serious reaction to ERANFU 250. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following

Frequent side effects:

- Urinary tract infections (bladder infection),
- Decreased blood platelet count (cells that help blood to clot),
- Lack or loss of appetite for food due to an emotional disorder where you have an unhealthy desire to lose weight by refusing to eat (anorexia),
- Headache,
- Hot flushes,
- Feeling sick (nausea), vomiting, loose stool (diarrhoea),
- Abnormal levels of liver enzymes (picked up in blood tests), increase of bile pigment produced by the liver (bilirubin),
- Rash,
- Joint, muscle and back pain,
- Feeling weak and a loss of energy (asthenia),
- Injection site reactions such as pain and/or inflammation,
- Numbness or tingling in your fingers and toes (peripheral neuropathy),
- Pain extending from your lower back to your leg (sciatica).

Less frequent side effects:

- Liver failure, increase of gamma-GT, which is a liver enzyme (picked up in a blood test),
- Thick, whitish or yellow vaginal discharge and candidiasis (vaginal infection),
- Bleeding at the injection site (injection site haemorrhage), a solid swelling of clotted blood within the tissues at the injection site (injection site haematoma).

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 health care professional. You can also report side effects to SAHPRA Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ERANFU 250.

5. How to store ERANFU 250

Your healthcare professional will be responsible for the correct storage, use and disposal of ERANFU 250.

ERANFU 250 must be stored at or below 25 °C.

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

The injection must not be used after the expiry date.

Store all medicines out of the sight and reach of children.

6. Contents of the pack and other information

What ERANFU 250 contains

The active substance is fulvestrant.

Each injection of ERANFU 250 contains 250 mg of fulvestrant.

The other ingredients of ERANFU 250 are alcohol (ethanol 96 %), benzyl alcohol, benzyl benzoate and castor oil.

What ERANFU 250 looks like and contents of the pack

ERANFU 250 is a clear, colourless to yellow viscous liquid.

The pre-filled syringe presentation consists of two 5 ml Clear Type - I glass syringe barrels with Original Vector System (OVS) Tip Cap, each containing 250 mg/5 ml of fulvestrant solution.

The pre-filled syringes are stoppered with grey-coloured fluorotec bromobutyl plunger stoppers.

The syringes come in a thermoformed blister tray with clear polystyrene plunger rods with two safety needles (SurGuard® 3 Safety hypodermic needles) with plastic needle shield.

Holder of Certificate of Registration

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For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd.

Tel: +27 11 324 2100

Other sources of information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories website:

http://www.drreddys.co.za