Initial submission: 31/10/2020
Response to Clinical recommendation as per SAHPRA email dated 01/04/2022: submitted 14/04/2022 (0004)

CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

FULDEXA

Solution for injection

Fulvestrant

Sugar free

Contains: Alcohol 96 %, benzyl alcohol, castor oil and benzyl benzoate

Read all of this leaflet carefully before you are given FULDEXA

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

1. What FULDEXAis and what it is used for

- FULDEXAcontains the active substance fulvestrant.

Initials:

- Fulvestrant belongs to the group of estrogen blockers. Estrogens, a type of female sex hormones, can in some cases be involved in the growth of breast cancer.

FULDEXAis used either:

- alone, to treat postmenopausal women with a type of breast cancer called estrogen receptor positive breast cancer that is locally advanced or has spread to other parts of the body (metastatic), or
- where the breast cancer has come back on or after adjuvant anti-oestrogen therapy, or if the breast cancer is progressing with an anti-oestrogen medicine.

2. What you need to know before you use FULDEXA

Do not use [PRODUCT NAME]:

- if you are allergic to fulvestrant or to any of the other ingredients of FULDEXA(listed in section 6)
- if you are pregnant or breast-feeding
- if you have severe liver problems

Warnings and precautions

Tell your doctor or health care provider before being given the injection of FULDEXAif any of these apply to you:

- kidney or liver problems
- low numbers of platelets (which help blood clotting) or bleeding disorders
- previous problems with blood clots
- osteoporosis (loss of bone density)
- alcoholism

Children and adolescents

FULDEXAis not indicated in children and adolescents under 18 years.

Other medicines and [PRODUCT NAME]

Always tell your health care 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).

Pregnancy and breast-feeding

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 before being given [PRODUCT NAME].

You must not use FULDEXAif you are pregnant. If you can become pregnant, you should use effective contraception (birth control) while you are being treated with FULDEXAand for 2 years after your last dose.

You must not breast-feed while on treatment with [PRODUCT NAME].

Driving and using machines

FULDEXAis not expected to affect your ability to drive or use machines. However, if you feel tired after treatment do not drive or use machines.

FULDEXAcontains alcohol 96 %.

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

Harmful for those suffering from alcoholism.

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

FULDEXAcontains benzyl alcohol. Benzyl alcohol may cause allergic reactions.

FULDEXAcontains 750 mg benzyl benzoate per injection.

3. How to use [PRODUCT NAME]

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

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

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

The recommended dose is 500 mg fulvestrant (two 250 mg/5 ml injections) given once a month, with an additional 500 mg dose given 2 weeks after the initial dose.

Your doctor or nurse will give you FULDEXAas a slow intramuscular injection, one into each of your buttocks.

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

If you receive more FULDEXAthan you should:

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Since a healthcare professional will administer [PRODUCT NAME], he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take FULDEXA

Since a healthcare professional will administer [PRODUCT NAME], it is unlikely that the dose will be missed.

4. Possible side effects

FULDEXAcan have side effects.

Not all side effects reported for FULDEXAare included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking [PRODUCT NAME], please consult your health care provider for advice.

You may need immediate medical treatment if you experience any of the following side effects:

• Allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat that may be signs of anaphylactic reactions

• Thromboembolism (increased risk of blood clots) *

• Inflammation of the liver (hepatitis)

• Liver failure

These are all very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. You may need urgent medical attention or hospitalization.

Tell your doctor, pharmacist, or nurse if you notice any of the following side effects:

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Frequent side effects

• Injection site reactions, such as pain and/or inflammation

• Abnormal levels of liver enzymes (in blood tests) *

• Nausea (feeling sick)

• Weakness, tiredness*

• Joint and musculoskeletal pain

• Hot flushes

• Skin rash

All other side effects

Frequent side effects

• Headache

• Vomiting, diarrhoea, or loss of appetite*

• Urinary tract infections

• Back pain*

• Increase of bilirubin (bile pigment produced by the liver)

• Thromboembolism (increased risk of blood clots) *

• Decreased levels of platelets (thrombocytopenia)

• Vaginal bleeding

• 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 side effects

• Thick, whitish vaginal discharge and candidiasis (infection)

• Bruising and bleeding at the site of injection

• Increase of gamma-GT, a liver enzyme seen in a blood test

• Inflammation of the liver (hepatitis)

• Liver failure

• Numbness, tingling and pain

* Includes side effects for which the exact role of FULDEXAcannot be assessed due to the underlying disease.

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 nurse>. This includes any possible side effects not listed in this leaflet. 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
[PRODUCT NAME].

5. How to store [PRODUCT NAME]

- Store in a refrigerator (2 °C – 8 °C).
- Temperature excursions outside 2 °C – 8 °C should be limited. This includes avoiding storage at temperatures exceeding 30°C, and not exceeding a 28-day period where the average storage temperature for the product is below 25 °C (but above 2 °C – 8 °C). After temperature

excursions, the product should be returned immediately to the recommended storage conditions (store and transport in a refrigerator 2 °C – 8 °C). Temperature excursions have a cumulative effect on the product quality and the 28-day time period must not be exceeded over the duration of the 4-year shelf life of [PRODUCT NAME]. Exposure to temperatures below 2 °C will not damage the product providing it is not stored below -20 °C.

- Store all medicines out of reach of children.
- Store the pre-filled syringe in original package until use, in order to protect from light
- Your healthcare professional will be responsible for the correct storage, use and disposal of [PRODUCT NAME]
- Do not use after the expiry date stated on the carton or syringe labels.
- 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 FULDEXAcontains

- The active substance is fulvestrant.
- Each pre-filled syringe (5 ml) contains 250 mg fulvestrant.
- The other ingredients are ethanol (96 %), benzyl alcohol, benzyl benzoate and refined castor oil.

What FULDEXAlooks like and contents of the pack

- A clear, colourless to yellow, viscous solution, filled in a clear glass pre-filled syringe. When examined under suitable conditions of visibility it should be practically free from foreign particles
- FULDEXAhas 2 pack presentations, either a pack containing 1 glass pre-filled syringe or a pack containing 2 glass pre-filled syringes. Safety needles (BD SafetyGlide) for connection to each barrel are also provided.

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Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park, Building 2

6 Coombe Place

Rivonia

Johannesburg

South Africa

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