PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

FULVEDEX 250 mg/5 ml injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe contains 250 mg/5 ml (5 % *w/v*) fulvestrant.
FULVEDEX contains ethanol 96 % 500 mg/5 ml (10 % *w/v*) and benzyl alcohol 500 mg/5 ml (10 % *w/v*).
Sugar free.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

FULVEDEX is a clear, colourless to yellow, viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

FULVEDEX is indicated for the treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:

- not previously treated with endocrine therapy, or
- with disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression with an anti-oestrogen.

4.2 Posology and method of administration

Posology

Adult females (including the elderly)

The recommended dose is 500 mg to be administered intramuscularly as two 5 ml injections, one in each buttock (gluteal area), at intervals of 1 month with an additional 500 mg dose given 2 weeks after the initial dose. It is recommended that the injection be administered slowly (1-2 minutes/injection).

Special populations

Patients with renal insufficiency

No dose adjustments are recommended for patients with a creatinine clearance greater than 30 mL/min. Safety and efficacy have not been further evaluated in patients with creatinine clearance less than 30 mL/min (see section 4.4).

Patients with hepatic insufficiency

No dose adjustments are recommended for patients with mild to moderate hepatic impairment. However, as fulvestrant exposure may be increased two-fold, FULVEDEX should be used with caution in these patients. Safety and efficacy have not been evaluated in patients with severe hepatic impairment (see section 4.3).

Elderly

No dose adjustment is required for elderly patients.

Interactions requiring dose adjustments

There are no known interactions requiring dose adjustments.

Paediatric population

Not recommended for use in children or adolescents, as safety and effectiveness have not been established in this age group.

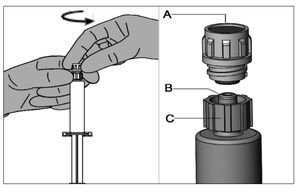
Method of administration

Administer intramuscularly slowly (1-2 minutes/injection) into the buttock (gluteal area). Caution should be taken if injecting FULVEDEX at the dorsogluteal site due to the proximity of the underlying sciatic nerve (see section 4.4).

Precautions to be taken before manipulating or administering FULVEDEX

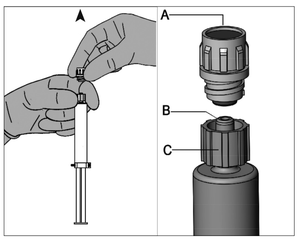
Warning - Do not autoclave safety needle (BD SafetyGlide™ Shielding Hypodermic Needle) before use. Hands must remain behind the needle at all times during use and disposal.
For each syringe: Remove glass syringe barrel from tray and check that it is not damaged. Peel open the safety needle (SafetyGlide™) outer packaging. Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.

Figure 1



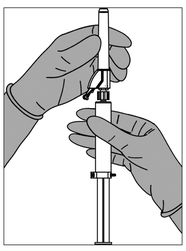
Hold the syringe upright on the ribbed part (C). With the other hand, take hold of the cap (A) and carefully twist the cap counter-clockwise until the cap disconnects for removal (see Figure 1).

Figure 2



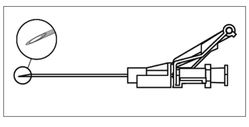
Attach the safety needle to the syringe tip (Luer-Lok) and twist until firmly seated (see Figure 3).

Figure 3



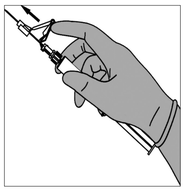
Check that the needle is locked to the Luer connector before moving out of the vertical plane.
Pull shield straight off needle to avoid damaging needle point.
Transport filled syringe to point of administration.
Remove needle sheath.
Expel excess gas from the syringe.
Administer intramuscularly slowly (1-2 minutes/injection) into the buttock (gluteal area). For user convenience, the needle bevel-up position is oriented to the lever arm (see Figure 4).

Figure 4



After injection, immediately apply a single-finger stroke to the activation assisted lever arm to activate the shielding mechanism (see Figure 5).

Figure 5



NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

4.3 Contraindications

- Hypersensitivity to fulvestrant or to any of the excipients (see section 6.1).
- Severe hepatic impairment.
- Pregnancy and breastfeeding.

4.4 Special warnings and precautions for use

FULVEDEX should be used with caution in patients with mild to moderate hepatic impairment (see sections 4.2 and 5.2).
Caution should be used before treating patients with creatinine clearance less than 30 mL/min (see section 4.2).
Caution should be used before treating patients with bleeding diatheses or thrombocytopenia or patients on anticoagulants due to the route of administration.
Injection site related events including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy have been reported with fulvestrant injection. Caution should be taken while administering FULVEDEX at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve (see section 4.2 and 4.8).
Thromboembolic events are commonly observed in women with advanced breast cancer and have been observed in clinical studies with fulvestrant (see section 4.8). This should be taken into consideration when prescribing FULVEDEX to patients at risk.
There are no long-term data on the effect of fulvestrant on bone. Due to the mechanism of action of fulvestrant, there is a potential risk of osteoporosis.

Hypersensitivity reaction

Hypersensitivity reactions such as angioedema and urticaria have been frequently reported and may be serious (see section 4.8).

Interference with oestradiol antibody assays

Due to the structural similarity of fulvestrant and oestradiol, FULVEDEX may interfere with antibody-based oestradiol assays and may result in falsely increased levels of oestradiol.

Alcohol

FULVEDEX contains ethanol (alcohol) 500 mg (10 % *w/v*) per injection. This may be harmful for those suffering from alcoholism and should be considered in high-risk groups such as patients with liver disease and epilepsy.

Benzyl alcohol

FULVEDEX contains benzyl alcohol as an excipient which may cause allergic reactions.

Paediatric population

FULVEDEX is not recommended for use in children and adolescents as safety and efficacy have not been established in this group of patients (see section 5.1).

4.5 Interaction with other medicines and other forms of interaction

Fulvestrant does not significantly inhibit any of the major cytochrome P450 (CYP) isoenzymes *in vitro*, and results from a clinical pharmacokinetic study involving co-administration of fulvestrant with midazolam also suggest that therapeutic doses of fulvestrant will have no inhibitory effects on CYP3A4.
In addition, although fulvestrant can be metabolised by CYP3A4 *in vitro*, a clinical study with rifampicin showed no change in fulvestrant clearance as a result of the induction of CYP3A4, and indirectly suggests that fulvestrant clearance would not be affected by CYP3A4 inhibitors. Results from a clinical study with ketoconazole, a potent inhibitor of CYP3A4, also indicated that there is no clinically relevant change in fulvestrant clearance. Dosage adjustment is not necessary in patients co-prescribed CYP3A4 inhibitors or inducers.
Due to the structural similarity of fulvestrant and oestradiol, fulvestrant may interfere with antibody-based oestradiol assays and may result in falsely increased levels of oestradiol.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Patients of childbearing potential should use effective contraception during treatment with FULVEDEX and for 2 years after the last dose.

Pregnancy

Studies in animals have shown reproductive toxicity.
FULVEDEX should not be used during pregnancy (see section 4.3).

Breastfeeding

Fulvestrant is found in rats' milk at levels significantly higher than those in rat plasma. The potential risk for humans is unknown.
FULVEDEX should not be used whilst breastfeeding (see section 4.3).

Fertility

The effects of fulvestrant, as in FULVEDEX, on fertility in humans has not been studied.

4.7 Effects on ability to drive and use machines

FULVEDEX is unlikely to impair the ability of patients to drive or operate machinery. However, during treatment with FULVEDEX, asthenia has been reported and caution should be observed by those patients who experience this symptom when driving or operating machinery.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently reported adverse reactions were injection site reactions, asthenia, nausea and increased hepatic enzymes (ALT, AST, ALP).
The frequency of adverse reactions listed below is defined using the following convention: frequent; less frequent or frequency unknown (cannot be estimated from the available data).

b. Tabulated summary of adverse reactions

MedDRA system organ class	Frequency	Adverse reactions
Infections and infestations	Frequent	Urinary tract infections
Blood and lymphatic system disorders	Frequent	Reduced platelet count
Immune system disorders	Frequent	Hypersensitivity reactions: angioedema and urticaria
	Less frequent	Anaphylactic reactions
Metabolism and nutrition disorders	Frequent	Anorexia
Nervous system disorders	Frequent	Headache
Vascular disorders	Frequent	Venous thromboembolism, hot flushes
Gastrointestinal disorders	Frequent	Nausea, vomiting, diarrhoea
Hepato-biliary disorders	Frequent	Elevated liver enzymes (ALT, AST, ALP), elevated bilirubin
	Less frequent	Hepatic failure, hepatitis, elevated gamma-GT
Skin and subcutaneous tissue disorders	Frequent	Rash
Musculoskeletal and connective tissue disorders	Frequent	Back pain, joint and musculoskeletal pain
Reproductive system and breast disorders	Frequent	Vaginal haemorrhage
	Less frequent	Vaginal moniliasis, leukorrhea
General disorders and administration site conditions	Frequent	Peripheral neuropathy, sciatica, injection site reaction, asthenia
	Less frequent	Injection site haemorrhage, injection site haematoma, neuralgia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Treatment

There is no human experience of overdosage. Animal studies suggest that no effects other than those related directly or indirectly to anti-oestrogenic activity were evident with higher doses of fulvestrant, as in FULVEDEX. If overdose occurs, this should be managed symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.21.12 Hormone inhibitors
Pharmacotherapeutic group: Endocrine therapy, Antioestrogens, ATC code: L02BA03.
Fulvestrant is an anti-oestrogen. Its mode of action leads to downregulation of oestrogen receptor protein and can be described as an oestrogen receptor downregulator (ER downregulator). Fulvestrant completely blocks the trophic actions of oestrogens without itself having any partial agonist activity. Fulvestrant binds to oestrogen receptors (ERs) in a competitive manner with an affinity comparable with that of oestradiol.
Fulvestrant is a reversible inhibitor of the growth of oestrogen-sensitive human breast cancer cells *in vitro*. Fulvestrant inhibits the growth of oestrogen-sensitive human breast cancer xenografts in nude mice. Fulvestrant inhibits the growth of tamoxifen-resistant breast cancer cells *in vitro* and of tamoxifen-resistant breast tumours *in vivo*.

5.2 Pharmacokinetic properties

Following intravenous or intramuscular administration, fulvestrant is cleared at a rate approximating to hepatic blood flow (nominally 10,5 ml plasma/min/kg). However, fulvestrant long-acting intramuscular injection maintains plasma fulvestrant concentrations within a narrow range (up to 3-fold) over a period of at least 28 days after injection. Administration of fulvestrant 500 mg achieves exposure levels at or close to steady state within the 1st month of dosing (mean [CV]): AUC 475 (33,4 %) ng.days/ml,
C_{max} 251 (35,3 %) ng/ml, C_{av} 16,3 (25,9 %) ng/ml, respectively. Results from single-dose studies of fulvestrant are predictive of multiple dose pharmacokinetics. No difference in fulvestrant pharmacokinetic profile was detected with regard to age (range 33 to 89 years).

Absorption

Fulvestrant is not administered orally.

Distribution

Fulvestrant's apparent volume of distribution at steady state was large (approximately 3 to 5 litre/kg), which suggests that the compound distribution is largely extravascular. Fulvestrant was highly (99 %) bound to plasma proteins at concentrations far in excess of those likely to be achieved in clinical use. VLDL, LDL and HDL lipoprotein fractions appear to be the major binding components. The role of sex hormone-binding globulin, if any, could not be determined. No studies were conducted on competitive protein binding interactions, as most reported interactions of this type involved binding to albumin and alpha-1-acid glycoproteins.

Biotransformation

Biotransformation and disposition of fulvestrant in humans have been determined following intramuscular and intravenous administration of ^{14}C-labelled fulvestrant. Metabolism of fulvestrant appears to involve combinations of a number of possible biotransformation pathways analogous to those of endogenous steroids, including oxidation, aromatic hydroxylation, and conjugation with glucuronic acid and/or sulphate at the 2-, 3- and 17-positions of the steroid nucleus, and oxidation of the side chain sulfoxide. The metabolism of fulvestrant in humans yields a similar profile of metabolites to that found in other species. Identified metabolites are either less active or exhibit similar activity to fulvestrant in anti-oestrogen models. Studies using human liver preparations and recombinant human enzymes indicate that CYP3A4 is the only P450 isoenzyme involved in the oxidation of fulvestrant, however non-P450 routes appear to be more predominant *in vivo*.

Elimination

Fulvestrant was cleared by the hepatobiliary route, the overall rate being determined by the mode of administration. Excretion was via the faeces and renal elimination of drug-related material was negligible (less than 1 %).

Hepatic impairment

The pharmacokinetics of fulvestrant has been evaluated in a single-dose clinical study conducted in women with mild to moderate hepatic impairment (Child Pugh class A and B). A shorter duration intramuscular injection formulation was used. There was up to a 2,4-fold increase in AUC in women with hepatic impairment compared to healthy women. Women with severe hepatic impairment (Child-Pugh class C) were not evaluated.

Effects on breast cancer tissue *in vivo*

Clinical studies in postmenopausal women with primary breast cancer have shown that fulvestrant downregulates ER expression in ER positive tumours. There was also a decrease in progesterone receptor (PR) expression (a marker of oestrogen action) consistent with the pre-clinical data demonstrating that fulvestrant lacks intrinsic oestrogen agonist activity. These changes in ER and PR expression were accompanied by reductions in expression of Ki67, a marker of tumour cell proliferation.

Effects on the postmenopausal endometrium

The pre-clinical data for fulvestrant suggest that it will not have a stimulatory effect on the postmenopausal endometrium. A study in healthy postmenopausal volunteers showed that compared to placebo, pre-treatment with 250 mg fulvestrant resulted in significantly reduced stimulation of the postmenopausal endometrium in volunteers treated with 20 mcg per day ethinyl oestradiol. This demonstrates a potent anti-oestrogenic effect on the postmenopausal endometrium.
Neoadjuvant treatment for up to 16 weeks in breast cancer patients treated with either fulvestrant 500 mg or 250 mg did not result in clinically significant changes in endometrial thickness, indicating of a lack of agonist effect. There is no evidence of adverse endometrial effects in the breast cancer patients studied.

Effects on bone

Neoadjuvant treatment for up to 16 weeks in breast cancer patients treated with either FASLODEX 500 mg or 250 mg did not result in clinically significant changes in serum bone-turnover markers. There is no evidence of adverse bone effects in the breast cancer patients studied.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96 %
Benzyl alcohol
Benzyl benzoate
Castor oil
Nitrogen (E941)

6.2 Incompatibilities

In the absence of compatibility studies FULVEDEX must not be mixed with other medicines.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store between 2 °C and 8 °C (in a refrigerator). Do not freeze. Protect from light. Store in the original carton until time of use.

6.5 Nature and contents of container

The pre-filled syringe presentation consists of 2 x 5 ml colourless, transparent pre-filled syringe barrels made of borosilicate glass (Type I), with a luer tip and a tip cap. It contains a grey fluoropolymer coated bromobutyl rubber plunger (5 ml). The two (2) syringes are presented in a tray with a plunger rod and fitted with a backstop. Two (2) safety needles (SafetyGlide) for connection to each barrel are also provided.
All of the above is kept in a carton to prevent light exposure.

6.6 Special precautions for disposal and other handling

Pre-filled syringes are for single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Kahma Biotech (Pty) Ltd
106, 16th Road
Midrand
1686
South Africa

8 REGISTRATION NUMBER

55/21.12/0531

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8 November 2022

10 DATE OF REVISION OF THE TEXT

Not applicable

312 x 728

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

FULVEDEX 250 mg/5 ml injection
Fulvestrant
Sugar free

Read all of this leaflet carefully before you start using FULVEDEX
- 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.

What is in this leaflet

1. What FULVEDEX is and what it is used for
FULVEDEX contains a medicine called fulvestrant which belongs to a class of medicines called hormone inhibitors. It blocks oestrogen, a type of female sex hormone, which can in some cases be involved in the growth of breast cancer.
FULVEDEX is used to treat:
- Breast cancer in postmenopausal women.

2. What you need to know before you use FULVEDEX
Do not use FULVEDEX:
- If you are hypersensitive (allergic) to fulvestrant or any of the other ingredients of FULVEDEX (listed in section 6).
- If you have severe liver (hepatic) problems.
- If you are pregnant or breastfeeding.

Warnings and precautions
Talk to your doctor before using FULVEDEX. Special care should be taken with FULVEDEX:
- 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 suffer from a loss of bone density (osteoporosis).

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 FULVEDEX and may need urgent medical attention or hospitalisation.

Children and adolescents
FULVEDEX is not recommended for use in children and adolescents.

Other medicines and FULVEDEX
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) FULVEDEX should not be given with oestradiol (female sex hormone), as it may result in falsely increased levels of oestradiol.

FULVEDEX with alcohol
FULVEDEX contains ethanol (alcohol) 500 mg (10 % *w/v*) per injection. This may be harmful if you suffer from alcoholism, liver disease or epilepsy.

FULVEDEX contains benzyl alcohol
Benzyl alcohol may cause an allergic reaction.

Pregnancy and breastfeeding
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 healthcare provider for advice. Do not use FULVEDEX if you are pregnant or during breastfeeding. If there is a possibility that you could become pregnant, then you should use an effective contraception during treatment with FULVEDEX and for 2 years after the last dose.

Driving and using machines
FULVEDEX 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 healthcare professional for advice.

3. How to use FULVEDEX
Do not share medicines prescribed for you with any other person. Always use FULVEDEX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will not be expected to give yourself FULVEDEX. It will be given to you by a person who is qualified to do so. Your doctor or nurse will give you the FULVEDEX 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 will decide the exact dose. FULVEDEX will be slowly injected into the muscle of each of your buttocks.

Your doctor will tell you how long your treatment with FULVEDEX will last. If you have the impression that the effect of FULVEDEX is too strong or too weak, tell your doctor or pharmacist.

If you receive more FULVEDEX than you should
Since a healthcare provider will administer FULVEDEX, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use FULVEDEX
Since a healthcare provider will administer FULVEDEX, it is unlikely that the dose will be missed.

4. Possible side effects
FULVEDEX can have side effects.

Not all side effects reported for FULVEDEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FULVEDEX, please consult your healthcare provider for advice.

If any of the following happens, stop using FULVEDEX and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Hypersensitivity (allergy) which include swelling of the face, lips, tongue and/or throat (angioedema) and itchy rash, weals and swelling of the skin (urticaria).

These are all very serious side effects. If you have them, you may have had a serious reaction to FULVEDEX. 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:
- Blood clots (venous thromboembolism)
- Liver failure
- Inflammation of the liver (hepatitis)

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

Tell your doctor if you notice any of the following:
Frequent
- Urinary tract infections (bladder infection)
- Reduced platelet count
- Skin rash (urticaria)
- Anorexia
- Headache
- Hot flushes
- Nausea (feeling sick), vomiting (being sick) and diarrhoea
- Abnormal levels of liver enzymes (in blood tests)
- Back, joint and musculoskeletal pain
- Vaginal bleeding
- Injection site reactions, such as pain and/or inflammation
- 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
- Anaphylactic reaction
- Increase of gamma-GT, a liver enzyme seen in a blood test
- 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 Reactions 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 FULVEDEX.

5. How to store FULVEDEX
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/ container until required for use
- Protect from light
- Do not use after the expiry date stated on the label / carton / bottle

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 FULVEDEX contains
- The active substance is fulvestrant.
- The other ingredients are ethanol 96 % 500 mg/ 5ml (10 % *m/v*), benzyl alcohol 500 mg/5 ml (10 % *m/v*), benzyl benzoate, castor oil and nitrogen (E941).

What FULVEDEX looks like and contents of the pack
FULVEDEX is a clear, colourless to yellow, viscous liquid.
The pre-filled syringe presentation consists of 2 x 5 ml colourless, transparent pre-filled syringe barrels made of borosilicate glass (Type I), with a luer tip and a tip cap. It contains a grey fluoropolymer coated bromobutyl rubber plunger (5 ml). The two (2) syringes are presented in a tray with a plunger rod and fitted with a backstop. Two (2) safety needles (SafetyGlide) for connection to each barrel are also provided.
All of the above is kept in a carton to prevent light exposure.

Holder of Certificate of Registration
Kahma Biotech (Pty) Ltd.
106, 16th Road, Midrand, 1686, South Africa.

Marketed by:
Eurolab (Pty) Ltd.

This leaflet was last revised in
8 November 2022

Registration number
55/21.12/0531

Access to the corresponding Professional Information
www.trinitypharma.co.za

L12285 K/22

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

FULVEDEX 250 mg/5 ml inspuiting
Fulvestrant
Suikervry

Lees hierdie inligtingstuk sorgvuldig voordat jy FULVEDEX begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorg verskaffer indien jy verdere vrae het

Wat in hierdie inligtingstuk is

1. Wat FULVEDEX is en waarvoor dit gebruik word
FULVEDEX bevat 'n medisyne wat fulvestrant genoem word wat behoort aan 'n klas medikasie wat hormoon inhibeerders genoem word. Dit blok estrogeen, 'n tipe vroulike geslagshormoon, wat in sommige gevalle betrokke kan wees in die groei van borskanker.
FULVEDEX word gebruik om die volgende te behandel:
- Borskanker in postmenopousale vroue.

2. Wat jy behoort te weet voordat jy FULVEDEX gebruik
Moet nie FULVEDEX gebruik:
- Indien jy hipersensitief (allergies) vir fulvestrant of enige van die bestanddele van FULVEDEX is nie.
- Indien jy ernstige lewer (hepatiese) probleme het.
- Indien jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter voordat FULVEDEX gebruik word. Spesiale sorg moet met FULVEDEX geneem word:
- Indien jy probleme met jou lewer of niere het.
- Indien daar vir jou gesê is dat jy 'n lae bloedplaatjie telling het, 'n bloedingsversteuring het of indien jy teenstolmiddels gebruik (medikasie om bloedklonte te voorkom).
- Indien jy ly aan 'n verlies van beendigtheid (osteoporose).

Hipersensitiwiteit (allergiese) reaksies:
- Hipersensitiwiteit (allergie), insluitend swelling van die gesig, lippe, tong en/of keel (angioëdeem), jeukerige uitslag, striemsels en swelling van die vel (urtikaria) is algemeen aangemeld en kan ernstig wees. Indien jy enige van hierdie simptome het, het jy moontlik 'n ernstige allergiese reaksie met FULVEDEX gehad en mag jy dringende mediese aandag of hospitalisasie benodig.

Kinders en adolessente
FULVEDEX word nie aanbeveel vir gebruik in kinders en adolessente nie.

Ander medisyne en FULVEDEX
Vertel altyd vir jou gesondheidsorg verskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.) FULVEDEX moet nie saam met estradiol (vroulike geslagshormoon) gegee word nie, aangesien dit tot vals verhoogde vlakke van estradiol mag lei.

FULVEDEX met alkohol
FULVEDEX bevat etanol (alkohol) 500 mg (10 % m/v) per inspuiting. Dit mag skadelik vir jou wees indien jy aan alkoholisme, lewersiekte of epilepsie ly.

FULVEDEX bevat bensielalkohol
Bensielalkohol mag 'n allergiese reaksie veroorsaak.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, vermoed dat jy dalk mag swanger wees of beplan om swanger te raak, raadpleeg jou dokter, apteker of ander gesondheidsorg verskaffer vir advies. Moet nie FULVEDEX gebruik indien jy swanger is of borsvoed nie. Indien daar 'n moontlikheid is dat jy swanger kan raak, moet jy 'n effektiewe voorbehoedmiddel gebruik tydens behandeling met FULVEDEX asook vir 2 jaar na die laaste dosis.

Bestuur en gebruik van masjinerie
FULVEDEX behoort nie jou vermoë om 'n motor te bestuur of masjinerie te gebruik, te beïnvloed nie. Party pasiënte mag egter af en toe moeg voel. Indien dit met jou gebeur, vra jou dokter, apteker of ander gesondheidsorg verskaffer vir advies.

3. Hoe om FULVEDEX te gebruik
Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Gebruik altyd FULVEDEX presies soos jou dokter of apteker vir jou gesê het. Maak seker by jou dokter of apteker indien jy onseker is.

Daar sal nie van jou verwag word om FULVEDEX vir jouself toe te dien nie. Dit sal aan jou toegedien word deur 'n persoon wat gekwalifiseerd is om dit te doen. Jou dokter of verpleegkundige sal vir jou die FULVEDEX inspuiting toedien. Die gewone dosis is 2 inspuitings eenmaal per maand toegedien, met 'n bykomende 2 inspuitings wat twee weke na die aanvanklike dosis toegedien word, maar jou dokter sal die presiese dosis bepaal.
FULVEDEX sal stadig in die spier van elke boud ingespuit word.

Jou dokter sal vir jou sê hoe lank jou behandeling met FULVEDEX sal duur. Indien jy onder die indruk is dat die effek van FULVEDEX te sterk of te swak is, sê vir jou dokter of apteker.

Indien jy meer FULVEDEX ontvang het as wat jy moes
Aangesien 'n gesondheidsorg verskaffer FULVEDEX vir jou gaan toedien, sal hy/sy die dosering kontroleer. In die geval van oordosering, sal jou dokter egter die oordosis bestuur.

Indien jy vergeet om FULVEDEX te gebruik
Aangesien 'n gesondheidsorg verskaffer FULVEDEX vir jou gaan toedien is dit onwaarskynlik dat 'n dosis gemis sal word.

4. Moontlike newe-effekte
FULVEDEX kan newe-effekte hê.
Nie al die newe-effekte wat vir FULVEDEX gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige onaangename gevolge ondervind terwyl jy FULVEDEX gebruik, kontak jou gesondheidsorg verskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van FULVEDEX en sê vir jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Hipersensitiwiteit (allergie), wat swelling van die gesig, lippe, tong en/of keel (angioëdeem) en jeukerige uitslag, striemsels en swelling van die vel (urtikaria) insluit .

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie teen FULVEDEX gehad het. Jy mag dringende mediese aandag of hospitalisering nodig hê.

Vertel onmiddelik vir jou dokter of gaan na die ongevalle departement van jou naaste hospitaal indien jy enige van die volgende waarneem:
- Bloedklonte (veneuse tromboëmbolisme)
- Lewerversaking
- Inflammasie van die lewer (hepatitis)

Hierdie is alles ernstige newe effekte. Jy mag dringend mediese aandig nodig hê.

Vertel jou dokter indien jy enige van die volgende waarneem:
Gereeld
- Urienweginfeksie (blaasinfeksie)
- Verminderde bloedplaatjietelling
- Vel uitslag (urtikaria)
- Anorieksie
- Hoofpyn
- Gloede
- Naarheid (siek gevoel), braking (siek word) en diarree
- Abnormale vlakke van lewerensieme (in bloedtoetse)
- Rug, gewrig en muskuloskeletale pyn
- Vaginale bloeding
- Inspuitingsplek reaksies, soos pyn en/of inflammasie
- Lae rug pyn wat na die been aan die een kant uitstraal (skiatika)
- Skielike swakheid, gevoelloosheid, tinteling, of verlies van beweging in jou been, veral net aan die een kant van jou liggaam, skielike probleme met loop of balans (perifere neuropatie)

Minder gereeld
- Anafilaktiese reaksie
- Verhoging van gamma-GT, 'n lewerensiem wat in bloedtoetse voorkom
- Dik, witterige vaginale afskeiding en kandidiase (infeksie)
- Kneusing en bloeding op die plek van inspuiting
- Gevoelloosheid, tinteling en pyn

Lig asseblief jou dokter of apteker in indien jy enige newe-effek ervaar wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van FULVEDEX.

5. Hoe om FULVEDEX te bewaar
Bewaar alle medisyne buite bereik van kinders
- Bewaar tussen 2 °C tot 8 °C (in 'n yskas)
- Moet nie vries nie.
- Beskerm teen lig.
- Moet nie na die vervaldatum op die etiket/karton/bottel gebruik nie.

Neem alle ongebruikte medisyne terug na jou apteker. Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting
Wat FULVEDEX bevat
- Die aktiewe bestanddeel is fulvestrant.
- Die ander bestanddele is etanol 96 % 500 mg/5 ml (10 % *m/v*), bensielalkohol 500 mg/5 ml (10 % *m/v*), bensielbensoaat, kasterolie en stikstof (E941).

Hoe FULVEDEX lyk en inhoud van die pak
FULVEDEX is 'n helder, kleurlose tot geel, viskeuse vloeistof.
Die voorafgevulde spuit se aanbieding bestaan uit 2 x 5 ml kleurlose, deursigtige voorafgevulde spuitvate gemaak van borosilikaatglas (tipe I), met 'n luerpunt en 'n punt dop. Dit bevat 'n grys fluoropolimeer-bedekte broombutiel rubbersuier (5 ml). Die twee (2) spuite word in 'n skinkbord met 'n suierstang aangebied en toegerus met 'n terugstop. Twee (2) veiligheids naalde (SafetyGlide) vir aansluiting aan elke vat, word ook voorsien. Al die bogenoemde word in 'n karton bewaar om blootstelling aan lig te voorkom.

Houer van die Registrasiesertifikaat
Kahma Biotech (Edms) Bpk.
16de Weg 106, Midrand, 1686, Suid Afrika.

Bemark deur:
Eurolab (Pty) Ltd.

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