PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

FASTELEV 250 mg/5 ml solution for injection

Fulvestrant

Read all of this leaflet carefully before you are given FASTELEV.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet:

1. What FASTELEV is and what it is used for.

2. What you need to know before you use FASTELEV.

3. How to use FASTELEV.

4. Possible side effects.

5. How to store FASTELEV.

6. Contents of the pack and other information.

1. What FASTELEV is and what it is used for:

FASTELEV contains the active substance fulvestrant, which belongs to the group of oestrogen blockers. Oestrogens, a type of female sex hormones, can in some cases be involved in the growth of breast cancer.

FASTELEV is used to treat advanced or metastatic breast cancer in postmenopausal women.

2. What you need to know before you use FASTELEV:

Do not use FASTELEV:

- if you are hypersensitive (allergic) to fulvestrant or to any of the other ingredients of **FASTELEV**
- if you have severe liver problems
- if you are pregnant or breastfeeding your baby.

Warnings and precautions:

Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with **FASTELEV**:

- if you have kidney or liver problems because the safety and effectiveness has not been evaluated in these instances
- if you have a low number of platelets (which help blood clotting) or bleeding disorders as **FASTELEV** will be given intramuscularly
- if you had previous problems with blood clots
- if you have osteoporosis (loss of bone density), because there is no long term data on the effect of **FASTELEV** on bone
- if you suffer from alcoholism, because **FASTELEV** contains alcohol.

Children and adolescents:

FASTELEV is NOT indicated in children and adolescents under 18 years, because the safety and effectiveness have not been established.

Other medicines and FASTELEV:

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

(This includes complementary or traditional medicines.)

You should tell your doctor if you are using anticoagulants (medicines to prevent blood clots).

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **FASTELEV.**

Pregnancy: You must not use **FASTELEV** if you are pregnant.

Breastfeeding: You must not breastfeed your baby while on treatment with **FASTELEV.**

Fertility: The effects of **FASTELEV** on fertility in humans has not been studied.

Contraception and newborn:

If you can become pregnant, you should use effective contraception while being treated with **FASTELEV.**

Driving and using machines:

FASTELEV 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.

FASTELEV contains alcohol:

FASTELEV contains ethanol (alcohol), the equivalent of 20 ml beer or 8 ml of wine, which is harmful for those suffering from alcoholism (drinking problem).

FASTELEV contains benzyl alcohol:

FASTELEV contains benzyl alcohol, which may cause allergic reactions.

3. How to use FASTELEV:

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

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

Adults and the elderly:

The usual dose is 500 mg **FASTELEV** (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 **FASTELEV** as a slow intramuscular injection, one into each of your buttocks.

If you use more FASTELEV than you should:

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

If you missed a dose of FASTELEV:

Since a healthcare professional will administer **FASTELEV**, it is unlikely that the dose will be missed.

4. Possible side effects:

FASTELEV can have side effects.

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

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

- allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat,
- rash or itching,
- fainting.

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

- urinary tract infections
- inflammation of the back of the throat (pharyngitis)
- anorexia (eating disorder)
- headache
- hot flushes
- nausea (feeling sick), vomiting, diarrhoea
- abnormal levels of liver enzymes (in blood tests)
- increase of bilirubin (bile pigment produced by the liver)

- back pain
- joint and muscle pain
- asthenia (an abnormal loss of strength)
- injection site reactions such as pain and/or inflammation
- sciatica (pain in the buttock, back of the thigh, or in the leg or foot)
- peripheral neuropathy (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).

Less frequent side effects:

- decreased levels of platelets (not enough platelets for your blood to clot – stop bleeding)
- elevated gamma-GT (indicator of injury related to the liver)
- vaginal bleeding, thick, whitish discharge and candidiasis (infection)
- bruising and bleeding at the site of injection
- neuralgia (acute spasmodic pain along the course of one or more nerves).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store FASTELEV:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store between 2 °C to 8 °C (in a refrigerator). Do not freeze.

Keep the pre-filled syringe in the original package, in order to protect from light.

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

Do not use **FASTELEV** if you notice visible particles and discolouration.

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 FASTELEV contains:

The active substance is fulvestrant. Each pre-filled syringe contains 250 mg fulvestrant. Each ml of solution contains 50 mg of fulvestrant.

The other ingredients (excipients) are benzyl alcohol, benzyl benzoate, refined castor oil, and ethanol (96 %).

What FASTELEV looks like and contents of the pack:

FASTELEV is a clear, colourless to yellow viscous solution in a pre-filled syringe fitted with a tamper evident closure, containing 5 ml solution for injection. Two syringes must be administered to receive the 500 mg recommended monthly dose.

Two (2) x 5 ml pre-filled syringes are packed in an outer cardboard carton.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

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Tel: 011 055 0200

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PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

S4

FASTELEV 250 mg/5 ml oplossing vir inspuiting

Fulvestrant

Lees hierdie hele blad noukeurig deur voordat FASTELEV aan u gegee word.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, vra asseblief vir u dokter of u apteker.

Wat in hierdie blad is:

1. Wat FASTELEV is en waarvoor dit gebruik word.

2. Wat u moet weet voordat u FASTELEV gebruik.

3. Hoe om FASTELEV te gebruik.

4. Moontlike newe effekte.

5. Hoe om FASTELEV te bêre.

6. Inhoud van die pak en ander inligting.

1. Wat FASTELEV is en waarvoor dit gebruik word:

FASTELEV bevat die aktiewe stof fulvestrant, wat tot die groep estrogeenblokkeerders behoort. Estrogene, 'n tipe vroulike geslagshormoon, kan in sommige gevalle betrokke wees by die groei van borskanker.

FASTELEV word gebruik om gevorderde of metastatiese borskanker in postmenopousale vroue te behandel.

2. Wat u moet weet voordat u FASTELEV gebruik:

Moenie FASTELEV gebruik nie:

- as u hipersensitief (allergies) teenoor fulvestrant of enige van die ander bestanddele van **FASTELEV** is
- as u ernstige lewerprobleme het
- as u swanger is of u baba borsvoed.

Waarskuwings en voorsorgmaatreëls:

Sê voordat u die inspuiting kry vir u dokter of mediese personeel:

Spesiale sorg moet met **FASTELEV** getref word:

- as u nier- of lewerprobleme het, omdat die veiligheid en effektiwiteit nie in hierdie gevalle beoordeel is nie
- as u 'n lae aantal bloedplaatjies het (wat bloedstolling help) of bloedingversteurings, aangesien **FASTELEV** binnespiers gegee word
- as u vorige probleme met bloedklonte gehad het
- as u osteoporose het (verlies aan beendigtheid), omdat daar geen langtermyndata oor die effek van **FASTELEV** op skeletbene is nie
- as u aan alkoholisme ly, omdat **FASTELEV** alkohol bevat.

Kinders en adolessente:

FASTELEV is NIE vir kinders en jongmense onder 18 jaar aangedui nie, omdat die veiligheid en effektiwiteit nie bepaal is nie.

Ander medisyne en FASTELEV:

Sê altyd vir u gesondheidspraktisyn as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).

U moet vir u dokter sê as u antikoagulante gebruik (medisyne om bloedklonte te voorkom).

Swangerskap, borsvoeding en vrugbaarheid:

As u swanger is of u baba borsvoed, moet u asseblief vir u dokter, apteker of ander gesondheidspraktisyn om advies vra voordat u **FASTELEV** gebruik.

Swangerskap: U moet nie **FASTELEV** kry as u swanger is nie.

Borsvoeding: U moet nie u baba tydens behandeling met **FASTELEV** borsvoed nie.

Fertiliteit: Die effek van **FASTELEV** op menslike fertiliteit is nie bestudeer nie.

Voorbehoeding en pasgebore:

As u swanger kan raak, moet u effektiewe voorbehoeding gebruik terwyl u met **FASTELEV** behandel word.

Motorbestuur en gebruik van masjinerie:

Dit word nie verwag dat **FASTELEV** u vermoë om ’n voertuig te bestuur of masjiene te gebruik sal beïnvloed nie. As u egter na die behandeling moeg voel, MOET NIE ’n voertuig bestuur of masjiene gebruik nie.

FASTELEV bevat alkohol:

FASTELEV bevat etanol (alkohol), wat die ekwivalent van 20 ml bier of 8 ml wyn is, wat skadelik is vir diegene wat aan alkoholisme ly (’n drankprobleem het).

FASTELEV bevat bensielalkohol:

FASTELEV bevat bensielalkohol, wat allergiese reaksies kan veroorsaak.

3. Hoe om FASTELEV te gebruik:

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

U dokter sal vir u sê hoe lank u behandeling met **FASTELEV** sal duur. Sê vir u dokter of apteker as u die indruk het dat die effek van **FASTELEV** te sterk of te swak is.

Volwassenes en bejaardes*:*

Die gewone dosis is 500 mg **FASTELEV** (twee inspuitings van 250 mg/5 ml) wat een keer per maand gegee word, met ’n bykomende dosis van 500 mg wat 2 weke na die aanvanklike dosis gegee word.

U dokter of verpleegster sal **FASTELEV** as ’n stadige binnespierse inspuiting, een in elkeen van u boude, gee.

As u meer FASTELEV gekry het as wat u moes:

Omdat ’n gesondheidspraktisyn **FASTELEV** sal toedien, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

As u ’n dosis FASTELEV oorgeslaan het:

Aangesien ’n gesondheidspraktisyn **FASTELEV** sal toedien, is dit onwaarskynlik dat ’n dosis oorgeslaan sal word.

4. Moontlike newe effekte:

FASTELEV kan newe effekte veroorsaak:

Nie al die newe effekte wat vir **FASTELEV** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe effekte ervaar terwyl u **FASTELEV** gebruik, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om **FASTELEV** te gebruik en onmiddellik vir u dokter sê of na die ongevalle afdeling van u naaste hospitaal gaan:

- allergiese (hipersensitiwiteits) reaksies, waaronder swelling van die gesig, lippe, tong en/of keel
- veluitslag of jeuk
- floutes.

Dit is almal baie ernstige newe effekte. As u dit ervaar, kan dit wees dat u ’n ernstige allergiese reaksie op **FASTELEV** het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- trombo-embolisme (hoër risiko vir bloedklonte)
- inflammasie van die lewer (hepatitis)
- lewerversaking.

Die bogenoemde is almal ernstige newe effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Dikwelse newe effekte:

- urienweginfeksies
- Inflammasie van die agterkant van die keel (faringitis)
- anoreksie (eetversteuring)

- hoofpyn
- gloede
- naarheid (mislike gevoel), braking, diarree
- abnormale vlakke van lewerensieme (in bloedtoetse)
- hoër vlakke bilirubien (galpigment wat deur die lewer geproduseer word)
- rugpyn
- gewrigs- en spierpyn
- astenie (’n abnormale verlies aan krag)
- reaksies by die inspuitplek soos pyn en/of inflammasie
- skiatika (pyn in die boude, agterkant van die dy, of in die been of voet)
- perifere neuropatie (skielike swakheid, gevoelloosheid, tinteling of verlies aan beweging in u been, veral aan slegs een kant van u liggaam, skielike probleme met loop of balans).

Minder dikwelse newe effekte:

- minder bloedplaatjies (nie genoeg bloedplaatjies om te stol nie - stop bloeding)
- hoër vlakke gamma-GT (aanduiding van beserings aan die lewer)
- vaginale bloeding, dik, witterige afskeiding en kandidiase (infeksie)
- pyn of kneusing by die plek van die inspuiting
- neuralgie (akute krampagtige pyn in die baan van een of meer senuwees).

As u enige newe effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe effekte:

Praat met u dokter, apteker of verpleegkundige as u enige newe effekte kry. Dit sluit alle moontlike newe effekte in wat nie in hierdie blad gelys word nie. U kan newe effekte ook via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf aanmeld.
Deur newe effekte aan te meld, kan u help om meer inligting oor die veiligheid van hierdie medisyne te gee.

5. Hoe om FASTELEV te bêre:

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Bêre tussen 2 ºC en 8 °C (in ’n yskas). Moenie vries nie.

Hou die voorafgevulde spuit in die oorspronklike karton om dit teen lig te beskerm.

Moenie **FASTELEV** gebruik na die vervaldatum wat na “EXP” op die karton of spuit gedruk is nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Moenie **FASTELEV** gebruik as u enige sigbare deeltjies of verkleuring sien nie.

Gee alle ongebruikte medisyne terug aan u apteker.

Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting:

Wat FASTELEV bevat:

Die aktiewe bestanddeel is fulvestrant. Elke voorafgevulde spuit bevat 250 mg fulvestrant. Elke ml oplossing bevat 50 mg fulvestrant.

Die ander bestanddele (hulpstowwe) is bensielalkohol, bensielbensoaat, geraffineerde kasterolie en etanol (96 %).

Hoe FASTELEV lyk en die inhoud van die pakkie:

FASTELEV is ’n helder, kleurlose tot geel viskose oplossing in ’n voorafgevulde spuit met ’n peutervrye seël, wat 5 ml oplossing vir inspuiting bevat. Twee spuite moet toegedien word om die aanbevole maandelikse dosis van 500 mg te ontvang.

Twee (2) voorafgevulde spuite van 5 ml elk is in ’n buitenste karton verpak.

Houer van die Registrasiesertifikaat en Vervaardiger:

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