1.3.2 Approved Patient Information Leaflet

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

FENDEXAM Film-coated tablets

Tamoxifen

Contains sugar: Lactose monohydrate 227.78 mg.

Read all of this leaflet carefully before you take FENDEXAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- FENDEXAM 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.
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What is in this leaflet:

1. What FENDEXAM is and what it is used for

FENDEXAM belongs to a group of medicines called anti-oestrogens and is used for the treatment of breast cancer.

2. What you need to know before you take FENDEXAM

Do not take FENDEXAM:

- If you are hypersensitive (allergic) to tamoxifen or any of the ingredients of FENDEXAM (listed in section 6).
- If you are pregnant or if you are breastfeeding.
- If you are taking any anticoagulants (blood thinning agents) such as warfarin
- If you are a women with a personal or family history of thromboembolism (blood clots),venous thromboembolism (or blood clots in the vein of the leg), stroke

Warnings and precautions

Tell your doctor or healthcare professional before taking FENDEXAM:

- If you have a history of stroke or blood clot;
- If you have liver disease;
- If you have high cholesterol or triglycerides (a type of fat in the blood);
- If you have a history of cataracts.
- if you have a history of deep vein thrombosis (blood clots in the veins of your legs), pulmonary embolism (blood clots in your lungs) or any clotting disorders. If you become aware of such events you should contact your doctor
- if you have low levels of white blood cells or platelets in your blood. This can make you bruise more easily, get serious infections, or feel very tired or breathless

- if you have high levels of calcium in your blood. Signs of this include feeling very thirsty, feeling sick (nausea) and vomiting

Tell your doctor immediately if you notice any of the following once you start treatment with FENDEXAM:

- Vaginal bleeding
- New breast lumps
- Pelvic pain or pressure
- Changes in your vision

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking FENDEXAM.

Children and adolescents

FENDEXAM has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and FENDEXAM:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

The use of FENDEXAM with these medicines may cause undesirable interactions.

In particular tell your doctor if you are using the following medicines:

- To thin your blood – eg. Warfarin;
- Chemotherapy;
- Letrozole (used for breast cancer);
- Anastrozole(used for breast cancer);
- Bromocriptine (used for pituitary tumours, increased prolactin in the blood).
- Rifampicin
- Medroxyprogesterone (contraceptive medicine)
- Aminoglutethimide

Pregnancy, breastfeeding and fertility

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 before taking this medicine.

You should not get pregnant while taking FENDEXAM or for two months after stopping treatment with FENDEXAM. Use a barrier contraceptive method or non-hormonal contraception (eg. condoms, diaphragm, spermicides, intrauterine devices), to prevent pregnancy.

FENDEXAM may harm your unborn baby if you are pregnant.

Do not breastfeed your baby while taking FENDEXAM. It may harm your baby.

Driving and using machines

It is not always possible to predict to what extent FENDEXAM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FENDEXAM affects them.

FENDEXAM contains lactose

FENDEXAM contains 227,78 mg of lactose monohydrate per film-coated tablet.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FENDEXAM.

3. How to take FENDEXAM

Do not share medicines prescribed for you with any other person. Always take FENDEXAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is one to two tablets, taken once a day or in divided doses taken twice a day.

Your doctor will tell you how long your treatment with FENDEXAM will last. Do not stop any treatment unless your doctor tells you to do so.
If you have the impression that the effect of FENDEXAM is too strong or too weak, tell your doctor or pharmacist.

If you take more FENDEXAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take FENDEXAM

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

FENDEXAM can have side effects.

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

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

- Pain and/or swelling in the legs;
- Sudden chest pain, shortness of breath and/or coughing up blood;
- Difficulty walking or talking, numbness and/or weakness;
- Vaginal bleeding, period irregularities, unusual vaginal discharge, pain or pressure in lower pelvis.

These are all very serious side effects which may indicate a stroke, blood clot or changes to your uterus (womb). If you have them, you may have had a serious reaction to FENDEXAM. You may need urgent medical attention or hospitalisation.

Treatment with FENDEXAM can very commonly cause hot flushes and changes in your period (menstruation).

Tell your doctor if you notice any of the following:

Frequent side effects:

- non-cancerous growths in the womb, cancer of the lining of the womb. this may cause pain or pressure in the pelvis (lower tummy) or irregular vaginal bleeding
- Weight gain
- Headaches
- Dizziness
- Hot flushes
- Coughing
- Nausea
- Stomach pain
- Leg cramps
- Bone pain
- Period irregularities
- Vaginal bleeding/discharge
- Itching of the genital area
- Water retention
- Weakness
- Hair loss
- Stroke/ DVT (deep vein thrombosis)
- anaemia (a blood condition which means you have too few red blood cells)

- itching of genitals

Less frequent side effects:

- Increase in blood calcium levels (hypercalcaemia). This may cause loss of appetite, nausea and vomiting, tiredness, weakness and muscle pain
- Dry cough and shortness of breath (Interstitial pneumonitis)
- Pancreatitis (pain or tenderness in your upper abdomen), mostly in patients with increased levels of fat in the blood before treatment with FENDEXAM
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema).
- Stevens -Johnson syndrome (a rare, serious disorder of the skin and mucous membranes, usually a reaction to medication)
- Inflammation of small blood vessels in the skin leading to skin rash (cutaneous vasculitis)
- Bullous pemphigoid(large, fluid-filled blisters).
- Erythema multiforme(bull's-eye-shaped lesions).
- Inflammation of the skin characterised by rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus)
- Presence of tissue similar to the lining of the uterus at other sites in the pelvis (endometriosis).
- Sharp dull pain in the lower abdomen accompanied by bloating and swelling. This may be due to swelling of the ovarian cyst
- Non-cancerous mass in the inner lining of the vagina (called vaginal polyp)

- Blisters on skin that's exposed to the sun, including the hands, face, and arms(Porphyria cutanea tarda)
- Radiation recall- a tissue reaction that develops on skin that previously received radiation therapy
- Cataracts
- Stroke
- Blood clots
- Lung disease
- Cancers of the uterus (womb)
- Liver problems
- Increase fat in the blood
- Lack of white blood cells (neutropenia)

Frequency unknown

- liver cancer
- loss of appetite,
- depression, confusion
- cerebrovascular accidents, (a loss of blood flow to part of the brain, which damages brain tissue)
- dizziness
- inflammation of the vein, cough
- swelling due to retained fluid
- severe increase in bone and tumour pain
- Weight gain
- stomach aches

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FENDEXAM.

5. How to store FENDEXAM

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the container in the outer carton in order to protect from light.

Do not use after the expiry date stated on the container and the carton.

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 FENDEXAM contains

The active substance is tamoxifen.

Each film-coated tablet contains 30,4 mg of tamoxifen Citrate, equivalent to 20 mg of Tamoxifen.

Contains sugar: lactose monohydrate 227,78 mg.

The other ingredients of FENDEXAM are:

Lactose Monohydrate, corn starch, povidone K 30, croscarmellose sodium, magnesium stearate, purified water.

Film-coating composition : Opadry white 02B58900 (hypromellose, titanium dioxide, macrogol/PEG), purified water.

What FENDEXAM looks like and contents of the pack

FENDEXAM is a white to off white, round, biconvex, unscored film-coated tablets debossed with ‘T20’ on one side and plain on the other side.

FENDEXAM film-coated tablets are packed in white opaque round 60 ml HDPE container closed with white opaque polypropylene child resistant 33 mm closure with wad having induction sealing liner, in a pre-printed carton with package leaflet.

Pack size: 30s

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NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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