PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

KESSAR® 20 Tablets

Tamoxifen citrate

Contains sugar

Each KESSAR 20 mg tablet contains 103,1 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking KESSAR

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

1. What KESSAR is and what it is used for

KESSAR is used to treat certain types of advanced breast cancer (that are estrogen receptor positive HER2).

KESSAR is also used to delay the recurrence of the cancer after surgically removing the breast for the treatment or prevention of cancer.

2. What you need to know before you take KESSAR

Do not take KESSAR

- if you are hypersensitive (allergic) to tamoxifen or any of the other ingredients of KESSAR (listed in section 6)
- if you are pregnant or breastfeeding

Warnings and precautions

Take special care with KESSAR:

- if you experience any abnormal vaginal bleeding, menstrual irregularities, vaginal discharge, pelvic pain or pressure, contact your doctor immediately as cancer, uterine tumours and other growths have been reported during treatment with KESSAR
- 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 are pre-menopausal as KESSAR prevents menstruation
- if you have high levels of calcium in your blood. Signs of this include feeling very thirsty, feeling sick (nausea) and vomiting
- if you have cataracts, eye damage or other vision problems

Gynaecological examinations, complete blood counts and liver function tests may be performed during your treatment with KESSAR. These tests may be needed to monitor your condition.

Other medicines and KESSAR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

KESSAR may interact with the following

- Warfarin, which is used to stop blood from clotting, as this could lead to bleeding risks.
- Medicines known as “aromatase inhibitors” that are used to treat breast cancer (e.g. anastrozole).

- Hormone preparations including the oral contraceptive pill as the effects of both KESSAR and the hormone preparation may be reduced.
- Medicines that are known to decrease renal (kidney) calcium excretion can cause an increase in calcium in the blood if taken with KESSAR. These medicines are diuretics; they cause an increase in urine excretion.
- Medicines used to treat cancer (e.g. tegafur, mitomycin).
- Medicines used to treat tuberculosis ('TB') (e.g. rifampicin).
- Antidepressants (e.g. paroxetine, fluoxetine).
- Quinidine (used to treat abnormal heart rhythm).
- Cinacalcet (used for treatment of thyroid disorders).
- Bupropion (used as an antidepressant or aid to smoking cessation).
- Aminoglutethimide (used to treat advanced breast cancer).
- Bromocriptine (used to treat excessive breast milk production or certain menstrual problems).

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 health care provider for advice before taking this medicine.

KESSAR should not be used if you are pregnant or breastfeeding.

Use an effective method of contraception during KESSAR therapy and for at least two months after discontinuation of KESSAR treatment. Ask your doctor for advice on what contraceptive to use - KESSAR affects how well some contraceptives work.

Driving and using machines

KESSAR can cause eye problems and fatigue (feeling tired). If you experience any of these symptoms, do not drive or use machinery.

It is not always possible to predict to what extent KESSAR 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 KESSAR affects them.

KESSAR contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take KESSAR

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

Always take KESSAR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended daily dose is 20 mg given in two divided doses (morning and evening) or as a single daily dose.

Your doctor will tell you how long your treatment with KESSAR will last. Do not stop treatment early.

A response is usually not achieved until after a treatment period of 2 to 3 months.

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

If you take more KESSAR 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 KESSAR

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

4. Possible side effects

KESSAR can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- severe skin rash with itching, redness, peeling of the skin or blistering in the mouth

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

- symptoms of a blood clot in the legs or lungs which include swelling of the calf or leg, chest pain, shortness of breath or suddenly feeling weak
- symptoms of a stroke which may include a sudden onset of weakness or paralysis of the arms or legs, sudden difficulty in speaking or walking, difficulty in holding things or difficulty in thinking

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:

- 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

- anaemia (a blood condition which means you have too few red blood cells)
- fluid retention (swelling of the hands, ankles and feet)
- stroke
- headache
- light-headedness
- sensory changes such as numbness or tingling of the skin (‘pins and needles’)
- taste disorder
- changes in vision due to cataracts or difficulty seeing due to changes to retina of your eye
- hot flushes
- clots in small blood vessels
- nausea (feeling sick)
- vomiting
- diarrhoea
- constipation
- change in liver function as shown in blood tests, formation of fatty liver cells
- skin rash
- loss of hair
- dry skin
- leg cramps
- muscular pain
- vaginal bleeding
- vaginal discharge
- itching of genitals
- changes in the womb (including changes to its lining)
- menstrual irregularities (including absence of menstrual period)
- fatigue (feeling tired)
- increased amount of fats in your blood as shown by blood tests

Less frequent side effects:

- cancer that forms in the muscle or tissue of the womb. a symptom of this may be unusual bleeding from the vagina that is not related to menstrual periods. a tumour flare reaction such as bone pain
- decrease in the number of white blood cells (leukopenia) and platelets in the blood (thrombocytopenia). this can make you bruise more easily or get severe infections. excessive bleeding
- high levels of calcium in your blood. signs of this include feeling very thirsty, feeling sick (nausea) and vomiting
- blurred vision and vision difficulties, swelling of the optic nerve, optic nerve damage, changes to the cornea of your eye
- inflammation of the lungs. the symptoms may be difficulty with breathing and coughing
- swelling of the pancreas. you may notice symptoms such as a pain in the stomach that moves to your back, fever and feeling sick
- serious liver abnormalities. the symptoms of these may be yellowing of the skin or eyes, dark coloured urine
- cells normally only found in the lining of womb may be found elsewhere in your body, cysts on the ovaries, non-cancerous growth in the inner lining of the vagina
- a skin condition in which blisters develop and turn into ulcers in areas exposed to sunlight, especially on the face, ears and back of the hands
- skin rash involving redness, swelling, and or blistering (like severe sunburn) after receiving radiation therapy

Other side effects:

- liver cancer
- loss of appetite, weight gain
- depression, confusion
- dizziness
- inflammation of the vein
- cough
- stomach aches

- swelling due to retained fluid
- severe increase in bone and cancer 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 or 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 KESSAR.

5. How to store KESSAR

- Store all medicines out of reach of children.
- Store at or below 25 ºC and protect from light.
- Do not use KESSAR after the expiry date which is printed on the label.
- 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 KESSAR contains

- The active substance of KESSAR is tamoxifen citrate. Each 20 mg tablet contains tamoxifen citrate equivalent to 20 mg tamoxifen.
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, povidone and sodium starch glycolate, purified water.

What KESSAR looks like and contents of the pack

KESSAR 20: White, round, convex, uncoated tablet, 9 mm in diameter embossed with "20" on the one side.

PVC/PVDC/Aluminum blister packs of 10 tablets in 30's and/or 250's.

40 ml high density polyethylene (HDPE) jar containing 30 tablets, closed with a 32 mm tamper-evident

HDPE closure

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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