PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

TAMOPLEX (Tablets)

Tamoxifen citrate equivalent to tamoxifen 20 mg

Contains sugar: 99,35 mg lactose monohydrate

Read all of this leaflet carefully before you start taking TAMOPLEX:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- TAMOPLEX 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 TAMOPLEX IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TAMOPLEX

3. HOW TO TAKE TAMOPLEX

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TAMOPLEX

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT TAMOPLEX IS AND WHAT IT IS USED FOR:

TAMOPLEX belongs to a group of medicines known as anti-oestrogens, which modify the effects of the female hormone, oestrogen.

TAMOPLEX is used for the treatment of breast cancer.

TAMOPLEX 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 TAMOPLEX:

Do not take TAMOPLEX:

- if you are hypersensitive (allergic) to tamoxifen or any of the other ingredients of TAMOPLEX (see **WHAT TAMOPLEX CONTAINS**).
- if you are not yet in menopause.
- if you are pregnant or breastfeeding a baby.

Warnings and precautions:

Take special care with TAMOPLEX:

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with TAMOPLEX treatment. Stop using TAMOPLEX and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in **section 4**.

Before you start to take TAMOPLEX, tell your doctor if:

- you have a history of hereditary angioedema as TAMOPLEX may cause or worsen symptoms of hereditary angioedema. If you experience symptoms such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing, contact a doctor immediately
- you are taking any anticoagulants (blood thinning agents) such as warfarin
- you have a personal or family history of thromboembolism (blood clots), venous thromboembolism (or blood clots in the vein of the leg) or stroke
- you are going to have breast reconstructive surgery
- you have bone cancer
- you have low blood counts which can make you bruise easily, feel very tired or out of breath.

You should inform your medical practitioner if you develop:

- vaginal bleeding, abnormal vaginal discharge, irregularities in your menstrual cycle or pelvic pain
- if you think you have a blood clot while taking TAMOPLEX. This is characterised by throbbing or cramping pain, swelling, redness and warmth in a leg or arm or sudden loss of breath and coughing up blood
- if you experience any disturbances in your vision while taking TAMOPLEX.

Your doctor may monitor your condition by conducting gynaecological examinations, blood tests and liver function tests during your treatment with TAMOPLEX.

Other medicines with TAMOPLEX:

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

Please consult your doctor, pharmacist or other healthcare professional for advice if you are taking:

- any anticoagulants (blood thinning medicines) such as warfarin
- medicines known as 'aromatase inhibitors' that are used to treat breast cancer (e.g. anastrozole)
- hormone preparations such as oral contraceptives or hormone replacement therapy (HRT) since their effects and TAMOPLEX may be reduced
- medicines that can increase your calcium levels such as high blood pressure medicines or water tablets
- a medicine known as aminoglutethimide used in the treatment of breast cancer
- bromocriptine (a medicine used to stop breastmilk production)
- anti-cancer medicines such as tefagur, mitomycin
- rifampicin (used to treat tuberculosis or TB)
- any medicines for the treatment of depression such as paroxetine or fluoxetine
- quinidine (used to treat an abnormal heartbeat)
- cinacalcet (used to treat the thyroid gland)
- bupropion (an anti-depressant medicine or an aid to stop smoking).

Pregnancy, breastfeeding and fertility:

TAMOPLEX should not be taken if you are pregnant or breastfeeding your baby.

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 become pregnant while taking TAMOPLEX and for nine months after you stop taking it.

Please see your doctor for contraception advice.

Men are recommended to use effective contraceptive measures (e.g. condom) and to not father a child while taking TAMOPLEX and for 6 months after you stop taking TAMOPLEX.

Driving and using machines:

TAMOPLEX may make you feel tired and sleepy and may disturb your vision. If you experience these symptoms you should refrain from driving or operating machinery.

TAMOPLEX contains lactose:

TAMOPLEX contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, or if you have the rare hereditary conditions of lactose or galactose intolerance, you should not take TAMOPLEX.

3. HOW TO TAKE TAMOPLEX:

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

Always take TAMOPLEX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

Adults including the elderly:

Unless otherwise directed, take one tablet daily. Swallow with a glass of water. Do not chew or crush the tablets.

Children:

TAMOPLEX is not recommended for children.

If you take more TAMOPLEX than you should:

Symptoms of swallowing many TAMOPLEX tablets include vertigo (dizziness, feeling unsteady on your feet), tremor (shaking of the arms, hands, feet), hyper-reflexia (overactive reflexes characterised by twitching), dysmetria (uncoordinated movements) and convulsions (fits).

In the event of an overdose, contact your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and any remaining tablets with you, so that the doctor knows what the person has taken.

If you forget to take TAMOPLEX:

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

If you stop taking TAMOPLEX:

Do not stop taking TAMOPLEX without speaking to your doctor first.

4. POSSIBLE SIDE EFFECTS:

TAMOPLEX can have side effects.

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

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

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms. These are the symptoms of side effects known as Stevens-Johnson syndrome and toxic epidermal necrolysis which occur rarely.

- rash, itching, swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing (angioedema). TAMOPLEX may cause or worsen symptoms of hereditary angioedema.
- blood clots in small or large blood vessels. If they occur in the larger blood vessels, you may notice symptoms such as swelling of the calf or leg, chest pain, coughing up blood, shortness of breath, sudden weakness, or sudden swelling of the hands, feet or ankles. You are more likely to suffer from these if you use TAMOPLEX in combination with other cytotoxic (anti-cancer) medicines.
- sudden confusion, weakness, loss of strength particularly on one side of the body, confused or loss of speech (these may be signs of a reduction on the blood flow to the brain).
- loss of vision.
- jaundice (yellow discoloration of the skin and eyes), abdominal pain, loss of appetite, nausea and vomiting and weakness. These are all symptoms of problems with your liver.

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

- vaginal bleeding, changes in your menstruation, pain in your pelvis
- heavy menstrual bleeding, enlargement of the lower abdomen area, lower back pain, increased urination (uterine fibroids)
- irregular or heavy menstrual bleeding. This could be a symptom of endometrial cancer or endometriosis
- worsening of the symptoms of your breast cancer (tumour flare)
- fainting
- swelling
- disturbances in your vision.

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

Tell your doctor if you notice any of the following which may occur frequently:

- decrease in blood iron levels characterised by fatigue, weakness, pale skin, dizziness and light-headedness

- headache
- prickling or burning sensation in your arms and legs (paraesthesia)
- altered taste perception (dysgeusia)
- changes in vision due to cataracts or changes to the retina of your eye
- hot flushes
- nausea (feeling sick) and vomiting
- diarrhoea
- constipation
- dry skin
- hair loss
- leg cramps
- muscle pain
- vaginal irritation
- changes to the lining of the uterus (endometrial hyperplasia)
- fatigue.

Tell your doctor if you notice any of the following which may occur less frequently:

- dry cough and shortness of breath (interstitial pneumonitis)
- swelling of the pancreas (pancreatitis) that may result in stomach pain radiating to the back, fever and nausea (feeling sick)
- decrease in the number of blood platelets (thrombocytopenia). This can cause unexpected bruising, bleeding from nose and gums, small purple or red dots under the skin
- decrease in number of blood cells that fight infection (leukopenia, neutropenia and agranulocytosis). This is characterised by fever, chills and sweating, irregular heartbeat, rapid breathing, mouth sores and shortness of breath
- increase in blood calcium levels (hypercalcaemia). This may cause loss of appetite, thirst, nausea and vomiting, tiredness, weakness and muscle pain
- elevation in the levels of triglycerides (certain type of fat) in your blood
- depression
- bone pain

- 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)
- weight gain
- recall phenomenon - a tissue reaction that develops on skin that previously received radiation therapy.

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 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 TAMOPLEX.

5. HOW TO STORE TAMOPLEX:

Store at or below 25 °C. Keep well-closed and protect from light.

Do not remove blisters from carton until required for use.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the label or blister.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

Do not store in a bathroom.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TAMOPLEX contains:

TAMOPLEX contains the active ingredient tamoxifen citrate which is equivalent to tamoxifen.

The other ingredients are:

Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose, potato starch, polyvidone.

What TAMOPLEX looks like and contents of the pack:

TAMOPLEX: White biconvex tablets with a diameter of 9 mm, without inscription.

Contents of pack:

TAMOPLEX tablets are packed in white plastic containers of 30, 100 and 250 tablets, or 3 blister strips of 10 tablets packed in a unit carton.

HOLDER OF THE CERTIFICATE OF REGISTRATION:

Teva Pharmaceuticals (Pty) Ltd,

Maxwell Office Park,

Magwa Crescent West,

Waterfall City,

Midrand,

Gauteng,

South Africa,

2090

Tel: (011) 055 0200

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