Package leaflet: Information for the user

Tamox 10mg Film-coated tablets
Tamox 20mg Film-coated tablets

Tamoxifen (as citrate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

1 What Tamox is and what it is used for

Tamox Tablets contain a medicine called tamoxifen citrate. Tamoxifen citrate is one of a group of medicines called anti-oestrogens, which modify the effect of the female hormone, oestrogen and it is used in the treatment of breast cancer.

2 What you need to know before you take Tamox

Do not take Tamox
- if you are allergic to tamoxifen or any of the other ingredients of this medicine (listed in section 6)
- if you have had blood clots in the past and the doctor did not know what caused them
- if someone in your family has had blood clots with the cause not known
- if your doctor has told you that you have an illness which runs in the family that increases the risk of blood clots
- if you are pregnant, about to become pregnant or breast-feeding.

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Tamox
- if you experience any abnormal gynaecological symptoms especially vaginal bleeding
- if you experience visual disturbances (while you are taking Tamox)
- if you have a history of hereditary angioedema, as tamoxifen 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 should also inform your doctor of any side effects you may have to the drug because if the side effects are severe it may be necessary to reduce the dose, or stop the treatment in any of the following situations:

- if you develop swelling or pain of the hands, feet or ankles (this could be due to a blood clot or thrombosis)
- if you have pain in the chest (this could be due to a blood clot in the lung)
- if you develop urticaria (nettle rash or hives).

In delayed breast reconstruction operation (weeks to years after the primary breast operation when your own tissue is moved to shape a new breast) Tamox may increase the risk of formation of blood clots in the small vessels of the tissue flap which may lead to complications.

Studies in premenopausal women who took tamoxifen for reduction of breast cancer risk or for treatment of breast cancer have reported decreases in bone density. If you are a premenopausal woman undergoing treatment with Tamox, ask your doctor for advice about ways to maintain your bone health.

Your doctor may give you blood tests (liver function tests, blood count and serum calcium), eye tests and gynaecological tests before and regularly while you are taking this medicine.

If you have any heart conditions including heart rhythm problems (arrhythmia), including a condition called Long QT syndrome (QT interval prolongation), the risk of heart rhythm problems may be increased when using Tamox.
Co-administration with the following drugs should be avoided because a reduction of the effect of tamoxifen cannot be excluded: paroxetine, fluoxetine (e.g. antidepressants), bupropion (antidepressant or aid to smoking cessation), quinidine (for example used in the treatment of cardiac arrhythmia) and cincalet/cinacalcet (for treatment of disorders of the parathyroid gland).

Other medicines and Tamox
Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular, you should inform your doctor if you are taking:
-medicines that contain hormones including the oral contraceptive pill
-an anti-coagulant (such as warfarin to prevent blood clots) or other drugs used to treat cancer
-paroxetine, fluoxetine (e.g. antidepressants)
-bupropion (antidepressant or aid to smoking cessation)
-quinidine (for example used in the treatment of cardiac arrhythmia)
-cinacalcet (for treatment of disorders of the parathyroid gland)
-rifampicin, a drug used to treat tuberculosis(TB)
-medicines known as “aromatase inhibitors” that are used to treat breast cancer e.g. anastrazole
-medicines known to affect heart rhythm.

Tamox with food and drink
Take Tamox Tablets whole with a drink of water.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Tamox if you are pregnant. This is because it may affect your unborn baby. Do not become pregnant while taking Tamox - see your doctor for contraceptive advice. If you are of child-bearing age, a pregnancy test should normally be taken before you start to take this medicine to confirm that you are not pregnant.

Women of childbearing age should use effective contraception during treatment with Tamoxifen and for 9 months after receiving the last dose.

Men are advised not to father a child during and up to 6 months following treatment with Tamoxifen and should therefore use effective contraception during treatment with Tamoxifen and for up to 6 months afterwards.

Breast-feeding
Women taking tamoxifen should not breast-feed, as tamoxifen may pass into breast milk.

Driving and using machines
Tamox is not likely to affect your ability to drive or use any tools or machines. However, tiredness has been reported with the use of tamoxifen and caution should be observed when driving or operating machines while such symptoms persist.

Tamox contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as it contains lactose.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3 How to take Tamox

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Recommended dose: The usual dose is 20-40 mg daily as a single or in divided doses twice daily, unless otherwise directed by your doctor. If you have breast cancer in an early stage, your doctor may recommend that you take your tablets for at least five years.

Children and adolescents
The use of Tamox is not recommended in children, as safety and efficacy have not been established.

If you take more Tamox than you should
Contact your doctor or pharmacist for advice or go to a hospital straightaway. Take the medicine pack with you so that the tablets can be identified.

If you forget to take Tamox
Do not take a double dose to make up for a forgotten dose. Take your tablets as soon as you remember, then go on as before. If it is almost time for your next dose, then do not take the missed dose at all. Do not take more than the total daily dose in 24 hours.

If you stop taking Tamox
Do not stop taking Tamox without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, particularly when you first start taking it, although not everybody gets them.

Stop taking Tamox and tell your doctor straightaway if you notice any of the following side effects - you may need urgent medical treatment.

- Symptoms of a blood clot. These include swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak.
- Symptoms of a stroke. These include sudden onset of the following: weakness of the arms or legs, being unable to move the arms or legs, difficulty speaking, walking or holding things, or difficulty thinking. These symptoms are caused by a reduced blood supply in the brain.
- Difficulty in breathing
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Tamoxifen may cause or worsen symptoms of hereditary angioedema.
- Swelling of the hands, feet or ankles
- Nettle rash (also called "hives" or "urticaria")
- 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 [Stevens-Johnson syndrome, toxic epidermal necrolysis] – these side effects occur rarely.

Tell your doctor straightaway if you notice any of the following:

- Unusual bleeding from your vagina
- Vaginal bleeding
- A feeling of discomfort in the lower tummy (pelvis) such as pain or pressure.

These effects may mean that there have been changes to the lining of your womb (the endometrium). Sometimes these effects are serious and could include cancer. They can happen during or after treatment with Tamox.

Other possible side effects:

Very common (may affect more than 1 user in 10)

- hot flushes
- nausea
- fluid retention
- skin rash
- fatigue
- vaginal discharge
- vaginal bleeding.

Common (may affect 1 to 10 users in 100):

- increased risk of blood clots (including clots in small vessels)
- anaemia (a blood problem which means you have too few red blood cells)
- changes in vision due to cataracts or changes to the retina of your eye
- increased amounts of fats in your blood (shown by blood tests)
- allergic reactions
- leg cramp
- changes in the womb (including changes to its lining and benign growths)
- vomiting
- diarrhoea
- constipation
- changes in blood test of liver function

- formation of fatty liver cells
- muscle pain
- sensory changes (including taste disorder and numbness or tingling of the skin
- genital itching
- thinning of the hair
- light-headedness
- headaches.

Uncommon (may affect 1 to 10 users in 1,000):
- blood problems. This can make you bruise more easily, get serious infections, or feel very tired or breathless.
- swelling of the pancreas. This may cause moderate to severe pain in the stomach.
- changes in the amount of calcium in your blood. The signs may include feeling very sick, being sick a lot or being thirsty. **Tell your doctor if this happens** because he or she may want you to have blood tests.
- inflammation of the lungs. The symptoms may be like pneumonia (such as feeling short of breath and coughing.
- liver cirrhosis
- changes in vision or difficulty seeing properly as a result of cataracts or changes to the retina
- stroke
- endometrial cancer.

Rare (may affect 1 to 10 users in 10,000):
- severe blood problems. These can make you bruise more easily, get serious infections , or feel very tired or breathless.
- changes to the cornea of your eye
- problems with the nerve that connects your retina to your brain
- swelling of the optic nerve
- on occasions more severe liver diseases have occurred from which patients have died. These liver diseases include inflammation of the liver, liver cirrhosis, liver cell damage, reduced bile formation, and failure of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes).
- damage to blood vessels causing red or purple dots in the skin
- severe skin disorder. The symptoms include redness, blistering and peeling.
- cells normally only found in the lining of the womb found elsewhere in your body cysts on the ovaries, and cancer (the signs of this are given above)
- non-cancerous mass in the inner lining of the vagina (called vaginal polyp)
- tumour flare.

Very rare (may affect less than 1 user in 10,000):
- inflammation of the skin characterized by rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus)
- a skin condition characterized by skin blisters in areas exposed to the light, this is due to the increased liver production of a special group of cell pigments (called porphyrins)
- very high levels of fatty liver cells with pancreatitis
- radiation recall – skin rash involving redness, swelling, and/or blistering of the skin after receiving radiation therapy

Not known (frequency cannot be estimated from the available data):
Decreased bone mineral density in premenopausal women
Changes in the electrical activity of the heart (Electrocardiogram QT Prolonged).

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 directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Tamox

Keep this medicine out of the sight and reach of children. Keep the blister in the outer carton in order to protect from light. Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Tamox contains
- The active substance is tamoxifen (as citrate). Two strengths of Tamox are available. They contain 10 mg and 20 mg tamoxifen (as citrate).

- The other ingredients are lactose monohydrate, povidone, sodium starch glycolate (type A), microcrystalline cellulose and magnesium stearate.
  The film-coating for the tablets is opadry white consisting of lactose monohydrate, titanium dioxide (E171), macrogol 4000 and hypromellose.

What Tamox looks like and contents of the pack
Tamox 10 mg and 20 mg Film-coated tablets are white, round, film-coated, biconvex tablets.

Tamox Tablets are blister packed in strips of 10 film-coated tablets each and are available in sales boxes of 10 and 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

MA Holder:
Rowex Ltd., Bantry, Co. Cork.

Manufacturers:
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

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