Package leaflet: Information for the user

Tamoxifen Rosemont 10 mg/5 ml Oral Solution

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 or your pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tamoxifen Rosemont is and what it is used for
2. What you need to know before you take Tamoxifen Rosemont
3. How to take Tamoxifen Rosemont
4. Possible side effects
5. How to store Tamoxifen Rosemont
6. Contents of the pack and other information

1. What Tamoxifen Rosemont is and what it is used for

The name of your medicine is Tamoxifen Rosemont (called Tamoxifen in this leaflet). It contains tamoxifen citrate. This belongs to a group of medicines called anti-oestrogens.

- Tamoxifen is used to treat breast cancer.
- Tamoxifen can also reduce the risk of developing breast cancer occurring in those women who have an increased likelihood of developing breast cancer (your risk). It is important that your healthcare professional calculates your risk of developing breast cancer and discusses the result with you before commencing treatment. There are a number of specific tools available to calculate breast cancer risk, based on information such as your age, family history, genetics, reproductive factors (e.g. age when periods started and stopped, had children or not, taken or taking hormonal replacement therapy and/or oral contraceptive pill) and history of breast disease. Although the tools can estimate your risk, it doesn't mean you will get breast cancer, being at increased risk means you have a higher chance of developing breast cancer. If you and your healthcare professional are considering using Tamoxifen for this, it is important to understand the benefits as well as the side effects of taking Tamoxifen because you don't currently have breast cancer and Tamoxifen reduces, but does not stop the risk of developing breast cancer.

If you want to know more about how to decide whether tamoxifen is right for you, there is more information for patients on the National Institute for Health and Care Excellence website. Ask your doctor to talk to you about the information which is available for patients.

How Tamoxifen works

Oestrogen is a natural substance in your body known as a 'sex hormone'. Some breast cancers need oestrogen to grow and Tamoxifen works by blocking the effects of oestrogen.

2. What you need to know before you take Tamoxifen Rosemont

Do not take Tamoxifen:
- if you are allergic (hypersensitive) to tamoxifen or any other ingredients in this medicine (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- if you are pregnant or breast feeding (see Section 'Pregnancy and breast-feeding')
- if you are taking anastrozole to treat breast cancer
- if you are taking any treatment for infertility
- 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 taking medicines used to prevent blood clots such as warfarin.

Children should not have this medicine.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Tamoxifen if:
- you or any member of your family have ever had strokes or blood clots.

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).

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

Tamoxifen therapy may be used to reduce the risk of breast cancer and it can be associated with serious side effects such as blood clots in the veins of your leg (deep vein thrombosis), blood clots in your lungs (pulmonary embolus) and uterine cancer, all of which can be fatal. Other less serious side effects such as hot flushes, vaginal discharge, menstrual irregularities and pelvis pain may also occur.

Whether the benefits of treatment outweigh the risks depends on your age, health history, your level of breast cancer risk and on your personal judgement. Tamoxifen therapy to reduce the risk of breast cancer may not be appropriate for all women at increased risk. All assessments with your healthcare professional of the potential benefits and risks prior to starting therapy are essential. You should understand that Tamoxifen reduces, but does not eliminate the risk of breast cancer.

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 Tamoxifen, ask your doctor for advice about ways to maintain your bone health.

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.

Serious skin reactions

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.

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

If you have or have had heart problems or an irregular heartbeat (arrhythmia), you may be at a higher risk of changes in your heart's electrical activity (known as QT prolongation) when using tamoxifen. QT prolongation can be seen on a heart test called an electrocardiogram (ECG) and may increase the risk of serious heart rhythm problems. If you are at an increased risk, your doctor should check your blood for important blood salts and minerals (electrolytes) and check your heart activity with an ECG before and during treatment with Tamoxifen.

Having operations and tests
- Your doctor may give you blood tests, eye tests and gynaecological tests before and while you are taking this medicine.

If you are going to have surgery, tell your doctor that you are taking Tamoxifen, particularly if you have ever had blood clots in the past as they may wish to consider stopping your treatment for a short period.

Other medicines and Tamoxifen

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Tamoxifen can affect the way some other medicines work.

Medicines that can affect your heart's electrical activity (known as QT prolonging medications). Taking these medicines with Tamoxifen may increase the risk of heart rhythm problems. Some common examples include certain antibiotics (erythromycin, clarithromycin) and some antidepressants and antipsychotics.

Also, some medicines can affect the way Tamoxifen works. In particular, tell your doctor if you are taking any of the following:
- paroxetine, fluoxetine (e.g. antidepressants)
- bupropion (antidepressants or aid to smoking cessation)
- quinidine (for example used in the treatment of cardiac arrhythmia)
- cincalet/cinacalcet (for treatment of disorders of the parathyroid gland)
- medicines known as 'aromatase inhibitors' that are used to treat breast cancer. These include anastrozole (used to treat breast cancer), letrozole and exemestane
- blood thinning medicines that stop clots from forming, such as warfarin, aspirin or clopidogrel. These are known as 'anti-coagulants'
- cancer medicines such as cyclophosphamide or you are having chemotherapy
- bromocriptine
- rifampicin used to treat tuberculosis (TB)
- medicines that contain hormones including the oral contraceptive pill
- hormone replacement therapy (HRT).

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

Contraception
- Women who can become pregnant should use adequate non-hormonal contraception (e.g., barrier contraception) during treatment with tamoxifen and for an additional nine months after stopping treatment. Talk to your doctor about this.

Pregnancy and breast-feeding
- Do not take this medicine if you are pregnant or breast-feeding. This is because it may affect your unborn baby.
- Do not become pregnant and avoid breast feeding whilst taking this medicine and for nine months after stopping treatment.
- If you think you have become pregnant you should speak to your doctor straight away
- As you should not become pregnant when taking tamoxifen, please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by tamoxifen.
- Talk to your doctor before taking tamoxifen if you are breast-feeding.

Driving and using machines
- Tamoxifen is not likely to affect your ability to drive or use any tools or machines. However, eye problems, dizziness and tiredness have been reported with the use of tamoxifen. If you experience this, do not drive or use machinery.
- The amount of alcohol in this medicine may also affect your ability to drive and use machinery.

Tamoxifen Rosemont contains:
- This medicine contains 750 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to 19 ml beer or 8 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.
  If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.
  If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- Sorbitol (E420) 1 g in each 5 ml. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.
- Glycerol (E422) which may cause headache, stomach upset and diarrhoea.
- This medicine contains 503.35 mg propylene glycol in each 5 ml.

3. How to take Tamoxifen Rosemont

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

Taking this medicine
- This medicine contains 10 mg of tamoxifen in each 5 ml of solution.
- Take this medicine by mouth.

Breast cancer treatment

Adults:
The usual dose for adults is:
- 20 mg each day.
- You may have this either as one dose or two doses.

Children:
Children should not have this medicine.

Reducing the risk of breast cancer

The recommended dose for reducing the risk of breast cancer is 20 mg daily for 5 years.

Your healthcare professional will calculate your risk of breast cancer occurring using information about you, your medical history and any family history of breast cancer.

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Continued overleaf

JOB INFORMATION

Product Name: Tamoxifen Oral Solution

Strength: 10mg/5ml
Pack Size: 150ml
Bottle Size: 150ml
Design Icon: N/A

New Item Code: G8KD1RBJ7
Previous Item Code: G8KD1RBJ6
Supplier Code: N/A
Change Control No.: CR-01839

JOB SPECIFICATION

Keyline Ref: UKL504
Dimensions: 640 x 170mm
Folded Size: 170 x 40mm
Tabbed: Yes
Pharmacode: 44
EAN Code: N/A
No. of Colours: 1
Page Number: 1 of 2

MAIN BODY TEXT

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Font Size: 9pt

COLOURS

Print Colours: Black

TECHNICAL NON PRINTING COLOURS

Keyline, Cirrus_Info_Box

ARTWORK VERSION: 2
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PRINT VERSION:
Date:
Operator:

APPROVALS

Third Party Approval
Name:
Sign:
Date:

Regulatory Approval
Name:
Sign:
Date:

If you take more Tamoxifen than you should

If you take more Tamoxifen than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Tamoxifen

- If you forget a dose, take the dose as soon as you remember unless it is nearly time for your next dose then go on as before.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Tamoxifen can cause side effects although not everybody gets them.

Stop taking Tamoxifen and tell a doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

- an allergic reaction. Signs may include any kind of skin rash, flaking skin, boils or sore lips and mouth, sudden wheezing, fluttering or tightness of the chest or collapse
- 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
- symptoms of a blood clot. The signs of this may include sudden shortness of breath, chest pain, coughing up blood, calf or thigh pain or swelling in the legs or suddenly feeling weak
- symptoms of a stroke. The signs of this may include sudden onset of weakness or paralysis of the arms or legs, sudden difficulty with speaking or walking, difficulty in holding things or difficulty in thinking. These may occur because the blood supply in the blood vessels of the brain is reduced
- 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').

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor straight away if you notice any of the following:

- unusual bleeding from your vagina
- changes in your period (e.g. irregular periods or heavier bleeding), discharge from your vagina or discomfort in the pelvis such as pain or pressure. This is because a number of changes to the lining of the womb may occur, some of which may be serious and could include cancer. They can happen during or after treatment
- swelling of the lungs. You may notice symptoms such as a dry cough, breathing becoming worse, swelling at the ends of the fingers, fever and a bluish discolouration of the skin.

Other possible side effects:

Very Common (may affect more than 1 in 10 people)

- fluid retention
- hot flushes
- feeling sick (nausea)
- skin rash
- discharge or unusual bleeding from your vagina
- tiredness
- depression.

Common (may affect up to 1 in 10 people)

- anaemia (a blood problem which means you have too few red blood cells)
- light-headedness, headache
- sensory changes including taste disorder and numbness or tingling of the skin
- changes in vision due to cataracts or changes to the retina of your eye
- being sick (vomiting), diarrhoea or constipation
- changes in blood tests of liver function
- thinning of your hair
- leg cramps or muscle pain
- genital itching
- changes to the womb (including changes to the lining and benign growths)
- formation of fatty liver cells
- bone and tumour pain
- increased level of fats in your blood (shown by a blood test)
- increased risk of blood clots (including clots in small vessels)
- allergic reactions.

Uncommon (may affect up to 1 in 100 people)

- blood problems. You may notice you bruise more easily, get serious infections, or feel very tired or breathless
- changes in your vision and difficulty seeing
- swelling of the pancreas (pancreatitis). You may notice symptoms such as a pain in the stomach that moves into your back, fever and feeling sick
- 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 (problems with your liver).

Rare (may affect up to 1 in 1,000 people)

- severe blood problems. Symptoms may include bleeding, bruising easily, feeling tired or weak and shortness of breath
- changes in your periods. Cells normally only found in the lining of the womb found elsewhere in your body, and cancer (the signs of this are given above). Cysts on the ovaries or a non-cancerous mass in the inner lining of the vagina (vaginal polyp)
- damage to blood vessels causing red or purple dots on the skin
- problems with your sight due to changes in your cornea or optic nerve diseases. In a small number of cases blindness
- problems with the nerve that connects your retina to your brain. Swelling of the optic nerve
- a severe rash with blisters or peeling of the skin and possibly blisters in the mouth and nose (Stevens-Johnson syndrome)
- on occasions more severe liver diseases have occurred from which some 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)
- severe skin disorder, skin rash, itching, swelling, blistering or peeling skin
- at the beginning of treatment, a worsening of the symptoms of your breast cancer such as an increase in pain and/or an increase in the size of the affected tissue may occur (known as tumour flare)
- changes in the electrical activity of the heart (ECG QT prolonged).

Very Rare (may affect up to 1 in 10,000 people)

- very high cholesterol levels
- inflammation of the skin characterised by a rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus)
- skin blisters in areas exposed to light due to increased liver production of a special group of cell pigments called porphyrins
- radiation recall - skin rash involving redness, swelling, and/or blistering (like severe sunburn) of the skin after receiving radiation therapy.

Not known (frequency cannot be estimated from the available data)

- decreased bone mineral density in premenopausal women.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Tamoxifen Rosemont

- Keep out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze.
- Store in the original package in order to protect from light.
- Discard 3 months after first opening.
- Do not use after the expiry date which is stated on the label and carton (Exp: month, year).
- The expiry date refers to the last day of that month.
- Do not use Tamoxifen Rosemont if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist.
- 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 to protect the environment.

6. Contents of the pack and other information

What Tamoxifen Rosemont Oral Solution contains

- The active ingredient is tamoxifen citrate. Each 5 ml of solution contains 10 mg of tamoxifen (as tamoxifen citrate).
- The other ingredients are ethanol (19% v/v), glycerol (E422), propylene glycol (E1520), sorbitol solution 70% (E420), natural aniseed flavouring (flavouring preparations, isopropyl alcohol, water), liquorice flavouring (flavouring preparations, natural flavouring substances, artificial flavouring substances, propylene glycol (E1520), isopropyl alcohol) and purified water.

What Tamoxifen Rosemont Oral Solution looks like and contents of the pack
A clear, colourless liquid with an odour of liquorice and aniseed It comes in a brown glass bottle holding 150 ml of solution.

Marketing Authorisation Holder and Manufacturer
Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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Rosemont®

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Date: 23.04.2026	Date:
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JOB INFORMATION

Product Name: Tamoxifen Oral Solution

Strength:	10mg/5ml	New Item Code:	G8KD1RBJ7
Pack Size:	150ml	Previous Item Code:	G8KD1RBJ6
Bottle Size:	150ml	Supplier Code:	N/A
Design Icon:	N/A	Change Control No.:	CR-01839

JOB SPECIFICATION

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COLOURS

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Keyline, Cirrus_Info_Box

APPROVALS

Third Party Approval	
Name:	
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Date:	
Regulatory Approval	
Name:	
Sign:	
Date:	