



Package leaflet: Information for the user

Tamoxifen Rosemont 10mg/5ml Oral Solution

Tamoxifen

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.

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.

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 cinacalcet/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.

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

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. 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)
- cinacalcet (for treatment of disorders of the parathyroid gland)
- anastrozole, used to treat breast cancer
- medicines that stop clots from forming, such as warfarin, aspirin or clopidogrel
- 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.

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

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 while taking this medicine or within 2 months of finishing the course.
- If you are sexually active, you should use a barrier method or other non-hormonal method of contraception. Talk to your doctor about this.
- If you think you have become pregnant you should speak to your doctor straight away.

Driving and using machines

- This medicine can cause eye problems, dizziness and tiredness. 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 5ml. The amount in 5ml 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) 1g in each 5ml. 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 503.35mg propylene glycol in each 5ml.

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

Adults:

The usual dose for adults is:

- 20mg to 40mg each day.
- You may have this either as one dose or two doses.

Children:

Children should not have this medicine.

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
- blistering or bleeding of the lips, eyes, nose and genitals. This could be a serious condition known as Stevens-Johnson syndrome
- 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
- 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.

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, 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
- changes in the amount of calcium in your blood. The signs may include feeling very thirsty, feeling sick (nausea) and being sick (vomiting). **Tell your doctor if this happens** because they may want to perform some blood tests
- 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
- yellowing of the skin and whites of the eyes (jaundice) which may be signs of liver problems. This could be a result of inflammation of the liver (hepatitis), liver cirrhosis, liver cell damage, formation of fatty liver cells, reduced bile formation or liver failure. In severe cases some patients have died.

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 your retina
- 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)
- bone and tumour pain
- increased level of fats in your blood (shown by a blood test).

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.

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

- changes in your periods, 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
- skin rash, itching, swelling, blistering or peeling skin.

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

- severe blood problems. Symptoms may include bleeding, bruising easily, feeling tired or weak and shortness of breath
- 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.

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.

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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 5ml of solution contains 10mg 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 150ml of solution.

Marketing Authorisation Holder

Perrigo Pharma International DAC,
The Sharp Building,
Hogan Place,
Dublin 2,
Ireland

Manufacturer

Omega Pharma International NV, Venecoweg 26, 9810 Nazareth, Belgium
Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Tamoxifen Rosemont 10mg/5ml Oral Solution
United Kingdom	Tamoxifen Rosemont 10mg/5ml Oral Solution

This leaflet was last revised in 09/2020