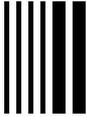
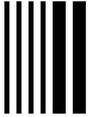


Soltamox 10mg/5ml Oral Solution Tamoxifen

Read all of this leaflet carefully before you start taking this medicine.



- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



In this leaflet:

1. What Soltamox is and what it is used for
2. Before you take Soltamox
3. How to take Soltamox
4. Possible side effects
5. How to store Soltamox
6. Further information

1. What Soltamox is and what it is used for

The name of your medicine is Soltamox. It contains tamoxifen citrate. This belongs to a group of medicines called anti-oestrogens.

Soltamox is used to treat breast cancer.

2. Before you take Soltamox

Do not take Soltamox and tell your doctor if:

- you are allergic (hypersensitive) to tamoxifen or any other ingredients in this liquid (listed in Section 6 below). The signs of an allergic reaction include a rash, itching or shortness of breath
- you are pregnant or breast feeding (see Section 'Pregnancy and breast-feeding')
- 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.

Take special care with Soltamox

Before you take Soltamox, tell your doctor if:

- you are pregnant (see Section 'Pregnancy and breast-feeding')
- 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 cinaclet/cinacalcet (for treatment of disorders of the parathyroid gland).

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

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 Soltamox, particularly if you have ever had blood clots in the past.

Taking other medicines

Please 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 Soltamox can affect the way some other medicines work. Also, some medicines can affect the way Soltamox 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 Soltamox.

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 and dizziness. 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.

Important information about what is in Soltamox

This medicine contains:

- liquid sorbitol (a type of sugar). If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine
- glycerol which may cause headache, stomach upset and diarrhoea
- 19%v/v ethanol (alcohol). Each 5ml dose contains 0.75g of alcohol equal to 19ml of beer or 8ml of wine. Speak to your doctor before taking this medicine if you have an addiction to alcohol, liver disease, epilepsy, brain injury or disease, you are pregnant or if this medicine has been prescribed for a child. It can also have an effect on other medicines you may be taking.

3. How to take Soltamox

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 10mg of tamoxifen in each 5ml
- 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 Soltamox than you should

If you take more Soltamox 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 Soltamox

- 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, Soltamox can cause side effects although not everybody gets them.

If you have any of the following stop taking Soltamox and see a doctor straight away if you have an allergic reaction to Soltamox

An allergic reaction 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.

If you have developed 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.

If you get any of the following side effects, see your doctor as soon as possible:

- 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
- feeling very thirsty, feeling sick (nausea) and being sick (vomiting). This may be a sign that you have too much calcium in your blood. Your doctor 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
- liver problems such as yellowing of the skin and whites of the eyes (jaundice) and inflammation of the liver (hepatitis).

Tell your doctor if you get any of these side effects:**Very Common (affect more than 1 in 10 people)**

- hot flushes, genital itching, discharge or unusual bleeding from your vagina.

Common (affect more than 1 in 100 people)

- light-headedness, headache
- feeling sick (nausea)
- thinning of your hair
- bone and tumour pain
- fluid retention
- leg cramps
- an increased risk of blood clots, deep vein thrombosis, pulmonary embolism (a blood clot in your lungs)
- changes in vision due to cataracts or changes to your cornea or retina.

Continued overleaf

Uncommon (affect more than 1 in 1000 people)

- being sick (vomiting)
- too much calcium in the blood (the signs of this are given above)
- optic nerve diseases, which cause problems with your sight.

Rare (affect more than 1 in 10,000 people)

- temporary blood problems. You may notice you bruise more easily. These usually disappear when you stop your treatment
- skin rash
- changes in your periods, changes to the lining of the womb, cysts on the ovaries, fibroids and cancer (the signs of this are given above)
- blindness.

Very Rare (affect less than 1 in 10,000 people)

- severe blood problems. You may notice you bruise more easily
- very high cholesterol levels
- 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
- damage to the cells in your liver
- severe skin rashes (Stevens Johnson syndrome). You may notice ring-shaped rashes and large blisters
- swelling of your lungs. (the signs of this are given above).

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.

5. How to store Soltamox

- Keep out of the reach and sight of children.
- Do not store above 25°C. Do not refrigerate or freeze.
- Store in the original package in order to protect from light.
- Get rid of the medicine 3 months after 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 Soltamox if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Soltamox contains

- The active ingredient is 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 Soltamox 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 and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last approved in February 2011

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