

Package Leaflet: Information for the User

Tamoxifen 10mg Tablets

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

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1. What Tamoxifen is and what it is used for

Tamoxifen belongs to a group of medicines known as anti-oestrogens. Tamoxifen is used to treat breast cancer.

2. Before you take Tamoxifen 10mg Tablets

Do not take Tamoxifen 10mg Tablets if you

are pregnant

are breast-feeding

are taking anticoagulant tablets?

have ever had an allergic reaction to tamoxifen or to any of its ingredients.

Tamoxifen should not be taken by women who are pregnant or breast feeding.

Taking other medicines

Tamoxifen 10mg Tablets can interact with certain types of anticoagulant medicine and a drug called rifampicin (for tuberculosis).

Please inform your doctor if you are taking, or have recently taken any other medicines, even those you have bought without prescription. In particular, you should inform your doctor if you are taking:

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)

3. Special Precautions

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).

Pregnancy

You should not become pregnant when taking Tamoxifen 10mg Tablets. Please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by tamoxifen. You should see your doctor immediately if you think you may have become pregnant after starting to take Tamoxifen 10mg Tablets.

Driving and using machines

There is no evidence to suggest that Tamoxifen 10mg tablets affect the ability to drive or use machines.

4. How to take Tamoxifen 10mg Tablets

Follow your doctor's instructions about when and how to take your medicine. Also read the label. Your pharmacist can also help if you are not sure.

The usual dose to treat breast cancer is 20mg daily. The daily dose can either be taken as a single dose every day or a dose can be divided in two and taken in the morning and the evening.

The dosage for infertility depends on the menstrual cycle. In women who are having regular periods treatment usually begins by taking 20mg of tamoxifen daily on the second, third, fourth and fifth days of the menstrual cycle. If this is not successful, your doctor may increase the dosage on these days to 40mg or 80mg daily.

In women who are not having regular periods, the treatment can be started on any day.

If you forget to take a dose, take it as soon as you remember and then carry on as before.

If you take more Tamoxifen 10mg tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

5. Possible side effects

Like all medicines Tamoxifen 10mg Tablets can cause side effects, although not everybody gets them.

Occasionally, a few people can suffer from stomach or gut upsets, headaches, light-headedness, menstrual disturbances, hot flushes, genital itching, vaginal discharge or bleeding, fluid retention, hypertriglyceridemia (increased levels of fat in your blood) sometimes with pancreatitis (pain or tenderness in your upper abdomen), skin rashes or itching or peeling skin, thinning of the hair, or inflammation of the lungs (which may present with the same symptoms as pneumonia, such as breathlessness and cough).

Other possible events are changes in vision or difficulty seeing properly as a result of cataracts or changes to the cornea or retina, an increased risk of blood clots, a tendency to bruise more easily, ovarian cysts or certain liver problems such as jaundice. Other possible events are effects on the endometrium (lining of the womb) which may also be seen as discomfort in the pelvis or as vaginal bleeding.

It is important that you tell your doctor immediately if you have any unusual vaginal bleeding, menstrual irregularities, vaginal discharge or discomfort in the pelvis such as pain or pressure when you are taking

tamoxifen or any time afterwards. This is because a number of changes to the lining of the womb (the endometrium) may occur, some of which may be serious and could include cancer.

At the beginning of treatment for breast cancer, the symptoms of the disease can sometimes get worse, for example an increase in pain or an increase in the size of the affected tissue. In addition, if you get excessive nausea, vomiting or thirst, tell your doctor because this may mean that there are changes in the amount of calcium in your blood and your doctor may want to check this.

Do not be alarmed by this list of possible events. You may not have any of them.

If you get any other undesirable effects or if you think your medicine is causing any problems, tell your doctor or pharmacist

STOP TAKING Tamoxifen 10mg Tablets and contact your doctor immediately in any of the following situations:

If you develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat.

If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty swallowing.

If you develop swelling of the hands, feet or ankles.

If you develop urticaria ('nettle rash' or 'hives')

6. How to Store Tamoxifen 10mg Tablets

Keep out of the reach and sight of children.

Do not store above 25°C. In order to protect from light, store in the original package.

Do not use after the expiry date shown on the carton and blister.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measure will help to protect the environment.

7. Further information

What Tamoxifen 10mg Tablets contain

The active substance (the ingredient which makes the medicine work) is tamoxifen (as citrate).

The other inactive ingredients are calcium hydrogen phosphate, microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate and colloidal anhydrous silica.

What Tamoxifen 10mg Tablets look like and contents of the pack

Tamoxifen 10mg Tablets are white, round tablets with a score line and 'TN10' embossed on one side and contain 10mg of tamoxifen.

Tamoxifen 10mg Tablets are available in Blister packs containing 30 or 250 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Relonchem Limited

27 Old Gloucester Street,

London WC1 3XX.

The Manufacturer is:

Heumann Pharma, Nuemberger Strasse 12, 90537 Feucht, Germany.

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