

Moxelle 20mg 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.

In this leaflet:

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1. What Moxelle is and what it is used for

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

It can also be used to treat infertility caused by a failure to ovulate properly.

2. Before you take Moxelle 20mg Tablets

Do not take Moxelle 20mg Tablets if you

are pregnant

are breast-feeding

are taking anticoagulant tablets?

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

are on concurrent anastrozole therapy

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

Taking other medicines

Moxelle 20mg Tablets can interact with certain types of anticoagulant medicine and a drug called rifampicin (for tuberculosis). Please ask your doctor or pharmacist before you take other medicines at the same time or if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

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 (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)

3. Special Precautions

Take special care

Co-administration with the following drugs should be avoided because a reduction of the effect of Moxelle 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).

Pregnancy

You should not become pregnant when taking Moxelle 20mg Tablets. Please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by Moxelle. You should see your doctor immediately if you think you may have become pregnant after starting to take Moxelle 20mg Tablets.

Driving and using machines

There is no evidence to suggest that Moxelle 20mg tablets affect the ability to drive or use machines.

4. How to take Moxelle 20mg 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 Moxelle 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 Moxelle 20mg 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 Moxelle 20mg 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).

Leg cramps have been reported commonly in patients receiving Moxelle 20mg Tablets.

Cases of optic neuropathy (Damage to optic nerves) have been reported in patients receiving Moxelle.

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 Moxelle 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 Moxelle 20mg 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 Moxelle 20mg 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 measures will help to protect the environment.

7. Further information

What Moxelle 20mg 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 Moxelle 20mg Tablets look like and contents of the pack

Moxelle 20mg Tablets are white, round tablets with a score line and 'TN20' embossed on one side and contain 20mg of Tamoxifen.

Moxelle 20mg Tablets are available in Blister packs containing 30 tablets.

Product Authorisation Holder and Manufacturer

Product Authorisation Holder:

Relonchem Limited

27 Old Gloucester Street,

London WC1 3XX.

The Manufacturer is:

Excella GmbH, Nuemberger Strasse 12, 90537 Feucht

Germany

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