

Chem mart® Tamoxifen

Tamoxifen Citrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Chem mart Tamoxifen. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking tamoxifen against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Chem mart Tamoxifen is used for

Tamoxifen tablets are used to stop or slow the growth of breast cancer cells.

Although women have been helped by tamoxifen it is not a cure for breast cancer.

Tamoxifen can be used in two ways. It can help treat a cancer which is in, or has spread from, the breast. It can also be used in women who have had a cancer lump removed, tamoxifen may decrease or prevent the spread of cancer cells to other parts of the body.

Tamoxifen belongs to a group of medicines called antiestrogens. Tamoxifen acts mainly by inhibiting the effects of oestrogen in the body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

Before you take Chem mart Tamoxifen

When you must not take it

Do not take tamoxifen if you have an allergy to:

- tamoxifen citrate
- other anti-oestrogen medicines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor may check you are not pregnant before prescribing this medicine.

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in tamoxifen passes into breast milk.

Do not give this medicine to children.

Safety and effectiveness have not been established in children.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- unusual or irregular vaginal bleeding or "spotting"
- liver problems
- blood clots
- a low white blood cell count, which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- a low blood platelet count, which you may notice as bleeding or bruising more easily than normal
- blurred vision or problems with the eyes.

Tell your doctor if you have not gone through menopause.

Tamoxifen is normally only given to women who have gone through menopause. If you are premenopausal menstruation will probably be suppressed. You may also develop cystic ovarian swellings while taking tamoxifen.

If you have not told your doctor about any of the above, tell him/her before you start taking tamoxifen.

Taking Other Medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and tamoxifen may interfere with each other. These include:

- other medicines used to treat cancer
- medicines used to prevent blood clots, including warfarin
- rifampicin, an antibiotic used to treat tuberculosis (TB)

These medicines may be affected by tamoxifen, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Chem mart Tamoxifen

Carefully follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide how much of this medicine you will need to take.

Most people will start their treatment by taking a 20 mg dose once daily. If no response is seen within one month, the dose may be increased to 40 mg once daily.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take tamoxifen before, with, or after food. However, taking it with food may help prevent stomach upsets.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much tamoxifen. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much tamoxifen the effects may include those listed in the 'side effects' section, but are usually of a more severe nature.

While you are taking Chem mart Tamoxifen

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking tamoxifen.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood tests along with some other tests from time to time to check on your progress and detect any unwanted side effects.

You should undergo routine gynaecological examinations if you are taking tamoxifen for a long time.

Things you must not do

Do not take tamoxifen to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking tamoxifen, or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how tamoxifen affects you.

This medicine may cause dizziness, light-headedness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

For sexual intercourse, use a barrier method such as a condom.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking tamoxifen.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- vaginal itching
- mild skin problems such as rash, itching, hives, dry skin or acne
- hot flushes
- dizziness or light-headedness
- changes in your menstruation (periods)
- hair loss or thinning
- indigestion or stomach upsets
- nausea and/or vomiting.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- problems with your eyesight
- swelling in your hands, feet or ankles

- unusual vaginal bleeding or discharge
- severe nausea and/or vomiting, constipation and stomach pain
- bleeding or bruising more easily than normal
- any signs of infection (such as fever, chills, sore throat, cough)
- tumour pain and flare, or bone pain

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- yellowing of the skin or eyes or dark coloured urine
- signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision, slurred speech, numbness in an arm or leg.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

After using Chem mart Tamoxifen

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store tamoxifen or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Chem mart Tamoxifen 20 mg tablets are round, flat, bevel-edged, white tablets, with "T" over "20" embossed on one face and a breakline on the other face.

They come in blister packs of 30 tablets.

Ingredients

Chem mart Tamoxifen tablets contain tamoxifen citrate as the active ingredient.

Chem mart Tamoxifen tablets also contain:

- lactose
- maize starch
- povidone
- colloidal anhydrous silica

- purified water
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

GenRx Pty Ltd
ABN 52 096 916 148
Level 21, 390 St Kilda Road
Melbourne, Victoria 3004
Australia

Distributor

Chem mart Pty Ltd
ABN 92 001 235 374
115 Sherriff Street
Underdale, South Australia
Australia 5032
Chem mart Tamoxifen 20 mg AUST R 75589
Chem mart® is a registered trade mark of FH Faulding & Co Limited
This leaflet was prepared in April 2004