



**Primus Ray
Laboratories**

TAMOXIFEN CITRATE 20mg

Tamoxifene Citrate 20 is approved for use for the following indication:

Tamoxifen is used to treat some types of breast cancer in men and women. It is also used to lower a woman's chance of developing breast cancer if she has a high risk (such as a family history of breast cancer).

Chemical: Tamoxifen citrate 20mg/tb
CAS Name: (Z)-2-[4-(1,2-Diphenyl-1-butenyl)phenoxy]-N,N-dimethyl-ethanamine-citrate; 1-p-beta-Dimethylaminoethoxyphenyl-trans-1,2-diphenylbut-1-ene citrate
Molecular Formula: C₂₆H₂₉NO.C₆H₈O₇
Molecular Weight: 563.64

Prescription Medicine

Tamoxifene Citrate 20
Each uncoated tablet contains:
Tamoxifene Citrate USP 20mg

INDICATION AND USES

Tamoxifen is used to treat some types of breast cancer in men and women. It is also used to lower a woman's chance of developing breast cancer if she has a high risk (such as a family history of breast cancer).

CONTRAINDICATIONS

You should not use tamoxifen if you are allergic to it.

You should not use tamoxifen to reduce your risk of breast cancer if you are also taking a blood thinner such as warfarin (Coumadin, Jantoven).

Do not take tamoxifen if you are pregnant. It could harm the unborn baby. Avoid becoming pregnant while you are using this medicine, and for at least 2 months after your treatment ends.

Hormonal contraception (such as birth control pills, injections, implants, skin patches, and vaginal rings) may not be effective enough to prevent pregnancy while taking tamoxifen. Ask your doctor about using non hormonal birth control (condom, diaphragm with spermicide, or intrauterine device/IUD).

If you are taking tamoxifen to reduce your risk of breast cancer, you may need to take your first dose while you are having a menstrual period. You may also need to have a pregnancy test before you start taking tamoxifen, to make sure you are not pregnant. Follow your doctor's instructions.

Taking tamoxifen may increase your risk of uterine cancer, stroke, or a blood clot in the lung, which can be fatal. Talk with your doctor about your specific risks in taking this medicine.

To make sure tamoxifen is safe for you, tell your doctor if you have:

- a history of stroke or blood clot;
- liver disease;
- high cholesterol or triglycerides (a type of fat in the blood);
- a history of cataracts; or
- if you are receiving chemotherapy or radiation.

It is not known whether tamoxifen passes into breast milk or if it could harm a nursing baby. This medicine may slow breast milk production. You should not breast-feed while taking tamoxifen.

PRECAUTIONS

Do not use tamoxifen if you are pregnant. It could harm the unborn baby. Use a barrier form of birth control (such as a condom or diaphragm with spermicide) while you are using this medication and for at least 2 months after your treatment ends. You should not use tamoxifen if you are allergic to it, or if you have a history of blood clots in your veins or your lungs, or if you are also taking a blood thinner such as warfarin (Coumadin).

Before using this medicine, tell your doctor if you have liver disease, high triglycerides (a type of fat in the blood), a history of cataract, or a history of stroke or blood clot. Also tell your doctor if you are receiving chemotherapy or radiation treatment.

If you are taking tamoxifen to reduce your risk of breast cancer, you may need to

take your first dose while you are having a menstrual period. You may also need to have a pregnancy test before you start taking this medicine, to make sure you are not pregnant. Follow your doctor's instructions.

Taking tamoxifen may increase your risk of uterine cancer, stroke, or a blood clot in the lung, which can be fatal. Talk with your doctor about your specific risks in taking this medication.

To make sure this medication is not causing harmful effects, your doctor may want you to have mammograms and to perform routine breast self exams on a regular basis. Your liver function may also need to be tested. Visit your doctor regularly.

DRUG INTERACTIONS AND SIDE EFFECTS

Because of the way this medicine acts on the body, there is a chance that it might cause unwanted effects that may not occur until months or years after the medicine is used. Tamoxifen increases the chance of cancer of the uterus (womb) in some women taking it. Tamoxifen may cause blockages to form in a vein, lung, or brain. In women, tamoxifen may cause cancer or other problems of the uterus (womb). It also causes liver cancer in rats. In addition, tamoxifen has been reported to cause cataracts and other eye problems. Discuss these possible effects with your doctor.

As well as its needed effects, tamoxifen may cause unwanted side effects that require medical attention.

If any of the following side effects occur while taking tamoxifen, check with your doctor immediately:

Less common or rare

- Anxiety
- blistering, peeling, or loosening of the skin and mucous membranes
- blurred vision
- cataracts in the eyes or other eye problems
- change in vaginal discharge
- chest pain
- chills
- confusion
- cough
- dizziness
- fainting
- fast heartbeat
- fever
- hoarseness
- lightheadedness
- lower back or side pain
- pain or feeling of pressure in the pelvis
- pain or swelling in the legs
- pain, redness, or swelling in your arm or leg
- painful or difficult urination
- rapid shallow breathing
- shortness of breath or trouble with breathing
- skin rash or itching over the entire body
- sweating
- weakness or sleepiness
- wheezing
- vaginal bleeding
- yellow eyes or skin

Incidence not known

- Bloating
- constipation
- darkened urine
- diarrhea
- difficulty with breathing
- indigestion
- itching
- joint or muscle pain
- large, hard skin blisters
- large hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, and sex organs
- loss of appetite
- nausea
- pain in the stomach or side, possibly radiating to the back
- red, irritated eyes
- red skin lesions, often with a purple center
- sore throat
- sores, ulcers or white spots in the mouth or on the lips
- unusual tiredness or weakness
- vomiting

Some tamoxifen side effects may not need any medical attention. As your body gets used to the medicine these side effects may disappear. Your health care professional may be able to help you prevent or reduce these side effects, but do check with them if any of the following side effects continue, or if you are concerned about them:

More common

- Absent, missed, or irregular periods
- decrease in the amount of urine
- feeling of warmth
- menstrual changes
- noisy, rattling breathing
- redness of the face, neck, arms and occasionally, upper chest
- skin changes
- stopping of menstrual bleeding
- swelling of the fingers, hands, feet, or lower legs
- troubled breathing at rest
- weight gain or loss
- white or brownish vaginal discharge

Less common or rare

- Abdominal or stomach cramps
- black, tarry stools
- bleeding gums
- blood in the urine or stools
- bluish color changes in skin color
- bone pain
- decreased interest in sexual intercourse
- discouragement
- feeling sad or empty
- hair loss or thinning of the hair
- headache
- inability to have or keep an erection
- irritability
- itching in the genital area
- loss of interest or pleasure
- loss in sexual ability, desire, drive, or performance
- nausea or vomiting (mild)
- pain
- pinpoint red spots on the skin
- skin rash or dryness
- stomach or pelvic discomfort, aching, or heaviness
- swelling
- trouble concentrating
- trouble with sleeping
- unusual bleeding or bruising

DOSAGE AND ADMINISTRATION

Usual Adult Dose for Breast Cancer

For the treatment of metastatic breast cancer in women and men:
20 to 40 mg orally Dosages greater than 20 mg should be given in divided doses (morning and evening).

For the treatment of women with Ductal Carcinoma in Situ, following breast surgery and radiation:
20 mg orally daily for 5 years.

To reduce the incidence of breast cancer in women at high risk for breast cancer:
20 mg orally daily for 5 years.

PRESENTATION:

20mg tablets in blister packs of 25 tablets – 2 packs per box (50 tablets)

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.