

GENOX

Tamoxifen (as citrate) Tablets 10 mg & 20 mg



What is in this leaflet

This leaflet answers some common questions about GENOX. It does not contain all the information available on this medicine. 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 GENOX against the benefits it is expected it will have for you. If you have concerns about using this medicine ask your doctor or pharmacist. Keep this leaflet with your medicine. You may need to read it again.

What GENOX is used for and how it works

GENOX is used to treat breast cancer.

GENOX tablets contain the active ingredient tamoxifen which works by blocking the actions of oestrogen, a female sex hormone. It belongs to a group of medicines known as non-steroidal anti-oestrogens.

Your doctor, however, may have prescribed GENOX for another reason. Ask your doctor if you have any questions about why GENOX has been prescribed for you.

GENOX is not approved for use in children.

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

There is no evidence that GENOX is addictive.

Before you take GENOX

When you must not take it

Do not use GENOX if:

- You are allergic to tamoxifen or any of the other ingredients listed at the end of this leaflet.
- You are pregnant.

Before you take it

Tell your doctor if:

- You have had an allergic reaction to any medicine that you have taken previously to treat your current condition.
- You think you might be pregnant or plan to become pregnant.
- You are breast feeding.

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.

GENOX should not be used during pregnancy as birth defects can result. A two month interval is recommended between stopping treatment and becoming pregnant.

GENOX is not recommended during breastfeeding as it is not known whether it passes into breast milk.

Do not take this medicine after the expiry date 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.

Taking other medicines

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

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

Some medicines that may interfere with GENOX include:

- Medicines used to prevent blood clots (anticoagulants) such as warfarin.
- Other medicines used to treat cancer.
- Rifampicin, an antibiotic.
- Paroxetine and fluoxetine which are used to treat depression.
- Bupropion which is an aid to stop cigarette smoking.

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

If you are not sure if you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take GENOX properly

Follow all directions given to you by your doctor or pharmacist.

How much to take

Your doctor will tell you how much GENOX you need to take each day. It is important that you take GENOX as directed by your doctor. Do not take more than the recommended dose.

The initial daily dose for adults and elderly patients is 20mg increasing to 40mg daily if necessary.

GENOX is not approved for use in children.

How to take it

Swallow the tablets with a glass of water at about the same time each day.

GENOX tablets can be taken with or without food.

If you forget a dose

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for the dose you missed. **If you are not sure what to do, ask your doctor or pharmacist.**

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking GENOX

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking GENOX.

If you are going to have any blood tests, remind your doctor that you are taking GENOX.

Tell your doctor if you develop a skin rash or hives.

Tell your doctor immediately if you become pregnant while taking GENOX or within two months of stopping treatment. This might require termination of pregnancy.

If you go into hospital let the medical staff know that you are taking GENOX.

Tell your doctor immediately if you notice unusual gynaecological symptoms, especially vaginal bleeding or discharge, even if it occurs after treatment with GENOX has stopped.

Unusual bleeding or discharge from the vagina are possible side effects of GENOX but they may also be symptoms of uterine or endometrial cancer. These along with other changes to the uterus lining (endometrium) have been reported in association with the use of this medicine.

Visit your doctor regularly so that he/she can check on your progress.

You will need to have regular gynaecological check-ups while you are taking GENOX. Your doctor may also order regular blood tests to check your calcium levels, white blood cell count and platelet counts.

Things you must not do

Do not take more tablets than your doctor tells you to.

Do not stop taking GENOX or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

Things to be careful of

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

GENOX may cause dizziness, light headedness or blurred vision in

some people. If this occurs do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- hot flushes
- nausea, vomiting
- any changes in your period
- unusual/changes in vaginal discharge
- itching around the genital area
- headache, dizziness or light-headedness
- diarrhoea or constipation
- skin rash
- fluid retention
- leg cramps
- unusual hair loss or thinning

These are the milder side effects of GENOX.

Rarely an increased level of triglycerides (fat in the blood) sometimes with pancreatitis (pain or tenderness in the upper abdomen) has been seen with GENOX.

Tell your doctor immediately if you notice any of the following:

- Abnormal vaginal bleeding (e.g. bleeding between periods, heavier than normal bleeding and bleeding after menopause).

- Unusual pain or pressure around your pelvis, in your bones or anywhere in your body
- Excessive thirst
- Swelling of the hands, ankles and feet
- Lower stomach pain or discomfort.
- Pain and reddening around the tumour
- Unusual tiredness, shortness of breath and dizziness when exercising, and looking pale
- Problems with vision
- Unexplained bruising
- Frequent infection, fever, severe chills, sore throat or mouth ulcers.
- Yellowing of the skin and eyes, and dark coloured urine.

If you have unusual vaginal bleeding or other gynaecological symptoms such as pelvic pain or pressure when you are taking GENOX or anytime afterwards, tell your doctor. This is because changes to the lining of the womb may occur, some of which may be serious.

Most of these are side effects are rare however you may need urgent medical attention.

Stop taking GENOX and tell your doctor immediately or go to your nearest Accident and Emergency if you experience any of the following symptoms:

- An unusual cough
- Severe pain in the chest which may reach the left arm
- Breathlessness
- Any unusual, severe or prolonged headache or migraine attack
- Partial or complete loss of vision, or double vision
- Slurring or speech disability
- Sudden changes to your hearing, sense of smell, or taste
- Dizziness or fainting
- Weakness or numbness in any part of your body
- Severe pain in your stomach
- Severe pain or swelling in either of your legs.

Increase risk of blood clots and ovarian cysts (in pre-menopausal

women) have been seen with GENOX

A blood clot is a very serious side effect. You may need urgent medical attention or hospitalisation.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Accident and Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any GENOX by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of GENOX with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack or if the packaging shows signs of tampering.

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

Store below 25°C and protect from light and moisture.

Keep GENOX out of reach of children. A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Do not store GENOX or any other medicine in the bathroom or near a sink. Do not leave GENOX in the car or on window sills.

Disposal

If your doctor tells you to stop taking GENOX or it has passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Date of information

25 July 2011
(Based on the data sheet dated 21 July 2011).

Product description

What it looks like

GENOX is available in two strengths:

- GENOX 10 a round white tablet marked "TN" over "10" on one side and G on the other side.
- GENOX 20 a round white tablet marked "TN" above a score and "20" under the score on one side and G on the other side.

List of other ingredients

Each GENOX tablet contains either 10mg or 20mg of the active ingredient tamoxifen (as tamoxifen citrate).

The tablets also contain

- mannitol
- maize starch
- croscarmellose sodium
- magnesium stearate.

GENOX tablets are lactose and gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792