

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about GENOX.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking GENOX against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What GENOX is used for

GENOX is used to treat breast cancer or reduce the risk of breast cancer occurring if you are at increased risk of breast cancer.

If you and your healthcare professional are considering using GENOX for reducing the risk of breast cancer occurring, your knowledge of treatment risks becomes more important because you don't currently have breast cancer. GENOX therapy may be uncommonly associated with serious side effects such as deep vein thrombosis (DVT - blood clots in veins of your leg), pulmonary embolus (blood clots in your lungs) and uterine cancer. In some women, these events were fatal. Less serious side effects such as hot flushes,

vaginal discharge, menstrual irregularities and gynaecological conditions may also occur. Whether the benefits of treatment outweigh the risks depends on your age, health history, your level of breast cancer risk and on your personal judgement. GENOX therapy to reduce the risk of breast cancer may not be appropriate for all women at increased risk for breast cancer. An assessment with your healthcare professional of the potential benefits and risks prior to starting therapy for reduction in breast cancer risk is essential. You should understand that GENOX reduces, but does not eliminate, the risk of breast cancer.

GENOX contains the active ingredient tamoxifen, which works by blocking the actions of estrogen. Estrogen is a natural female sex hormone. In some types of breast cancer, estrogen can help cancer cells to grow.

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

Your doctor may have prescribed GENOX for another reason.

GENOX is not approved for use in children.

This medicine is available only 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 take GENOX if you are allergic to medicines containing tamoxifen or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- skin rash, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath.

Do not take GENOX if you are pregnant or plan to become pregnant.

GENOX should not be used during pregnancy. A small number of unwanted complications, such as birth defects, have been reported in the unborn baby of women who have taken this medicine. However, it has not been shown whether these were due to GENOX. If sexually active, your doctor may suggest you use a non-hormonal form of contraception while you are taking GENOX and for nine months after you have stopped treatment with it.

Do not take GENOX if you are breastfeeding.

GENOX is not recommended during breastfeeding as your baby may take in GENOX from breast milk.

Do not use GENOX for reducing the risk of breast cancer occurrence if:

- you are taking medicines used to prevent blood clots such as warfarin
- you have had deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs).

Do not give GENOX to children.

There is no experience of its use in children.

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

Before you start to take it

Tell your doctor if you are allergic to:

- tamoxifen, the active ingredient in GENOX
- any of the other ingredients in GENOX listed at the end of this leaflet
- other anti-estrogen medicines
- any other medicines
- any other medicines, foods, dyes or preservatives.

Tell your doctor if you have not been through menopause.

Tell your doctor if you plan to become pregnant or breastfeed.

GENOX is not recommended for use in pregnancy and breastfeeding.

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

- a history of hereditary angioedema (as GENOX may cause or worsen symptoms of hereditary angioedema)
- liver problems
- any blood disorder or problems such as thrombocytopenia or leucopenia
- unusual or unexplained vaginal bleeding or discharge
- deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs).

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking GENOX.

Taking other medicines

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 may be affected by GENOX, or may affect how well it works. These include:

- oral contraceptives ('the pill')
- hormone replacement therapy
- other medicines used to treat cancer
- medicines used to prevent blood clots such as warfarin
- rifampicin, an antibiotic
- chemotherapy
- any medicines that you buy at the chemist supermarket or health food shop.

GENOX should not be taken with aromatase inhibitors such as anastrozole, letrozole or exemestane.

These medicines may affect the way GENOX works.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether 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 GENOX.

How to take GENOX

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

The usual starting dose is 20 mg once a day. Your doctor may increase this dose to 40 mg a day, depending on your condition and how you respond to the medicine.

Patients with liver problems may need smaller doses.

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. Do not chew or crush the tablets.

GENOX tablets can be taken with or without food.

How long to take it

Keep taking GENOX for as long as your doctor recommends.

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 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.

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 GENOX.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

There have been reports of heart rhythm problems associated with an overdose of this medicine.

While you are taking GENOX

Things you must do

If you are about to be started on any 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 go into hospital, please let the medical staff know that you are taking GENOX.

Tell your doctor immediately if you become pregnant while taking GENOX, or within nine months of stopping treatment.

Tell your doctor immediately if you notice any 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 they 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 and platelet counts.

Things you must not do

Do not breastfeed while you are taking GENOX.

Do not take GENOX 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 your medicine or change the dosage without checking with your doctor.

Things to be careful of

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

GENOX may cause dizziness, lightheadedness or fatigue in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

GENOX helps most people with breast cancer, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some are associated with treatment with GENOX and some may arise from the breast cancer itself. You may need medical treatment if you get some of the side effects.

Some people, such as those who have not had menopause, may have a greater risk of getting some of these 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 doctor if you notice any of the following and they worry you:

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

The above list includes the milder side effects of your medicine.

Rarely an increased level of triglycerides (increased levels of fats 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:

- unusual pain or pressure around your pelvis, in your bones or anywhere in your body
- excessive thirst
- swelling of the hands, ankles and feet
- any changes in your vision
- pain and reddening around the tumour
- lumps anywhere in the body
- unusual tiredness, shortness of breath and dizziness when exercising, and looking pale
- frequent infection, fever, severe chills, sore throat or mouth ulcers
- unexplained bruising
- yellowing of the skin or eyes, dark coloured urine
- disturbances of vision

Cases of optic nerve diseases have been reported in patients receiving tamoxifen and, in a small number of cases, blindness has occurred.

If you have any 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 a number of changes to the lining of the womb (endometrium) may occur, some of which may be serious and could include cancer.

GENOX may decrease bone density in premenopausal women. It is not known if this increases the risk of fractures. Ask your doctor for advice about ways to maintain your bone health.

GENOX may cause or worsen symptoms of hereditary angioedema.

The above list includes serious side effects which may require medical attention. Many of these side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- rash, itching or hives
- swelling of the face, lips, tongue and/or throat, difficulty in swallowing or breathing (angioedema)
- wheezing with difficulty breathing
- sudden onset of weakness or paralysis of the arms or legs, sudden difficulty with speaking walking, difficulty in holding things or difficulty in thinking, any of which may occur because the blood supply in the blood vessels of the brain is reduced. These symptoms could be signs of a stroke.

Increased risk of blood clots and ovarian cysts (in premenopausal women) have been seen with GENOX.

The side effects listed above are serious and require urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects.

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

After taking GENOX

Storage

Keep GENOX 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.

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 the tablets away from light.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking GENOX, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

GENOX is available in 2 strengths:

- GENOX 10 - round, white tablet marked "TN" over "10" on one side and "G" on the other side.
- GENOX 20 - round, white, scored tablet marked "TN" over "20" on one side and "G" on the other side.

Each pack contains 30 or 60 tablets.

Ingredients

The active ingredient in GENOX is tamoxifen (as tamoxifen citrate).

- Each GENOX 10 tablet contains 10 mg of tamoxifen.
- Each GENOX 20 tablet contains 20 mg of tamoxifen.

The tablets also contain the following inactive ingredients:

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

The tablets are gluten free.

Supplier

GENOX is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration numbers:

GENOX 10 - AUST R 40063

GENOX 20 - AUST R 40065

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