

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking GENOX?

GENOX contains the active ingredient tamoxifen citrate. GENOX is used to either treat breast cancer or reduce the risk of breast cancer occurring if you are at increased risk of breast cancer.

For more information, see Section [1. Why am I taking GENOX?](#) in the full CMI.

2. What should I know before I take GENOX?

Do not take if you have ever had an allergic reaction to tamoxifen citrate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take GENOX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GENOX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take GENOX?

- The usual dose is 20 mg of GENOX each day. Your doctor may increase your dose to 40 mg a day depending in your condition and how you respond to the medicine.
- **Swallow your GENOX whole, with a full glass of water. Do not chew or crush the tablets.**

More instructions can be found in Section [4. How do I take GENOX?](#) in the full CMI.

5. What should I know while taking GENOX?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none"> • Tell any other doctors, dentists and pharmacists who are treating you that you are taking GENOX. • Tell your doctor immediately if you notice any unusual gynecological symptoms, especially vaginal bleeding or discharge, even if it occurs after treatment with GENOX has stopped. • If you go into hospital, please let the medical staff know that you are taking GENOX. |
| Things you should not do | <ul style="list-style-type: none"> • Do not stop taking GENOX, or lower the dosage, unless you have discussed this with your doctor. • Do not take GENOX to treat any other complaints unless your doctor tells you to. • Do not get pregnant while you are taking GENOX and for nine months after you stop taking GENOX. • Do not breastfeed while you are taking GENOX. |
| Driving or using machines | <ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how GENOX affects you. |
| Looking after your medicine | <ul style="list-style-type: none"> • Keep your GENOX tablets in the blister pack until it is time to take them. • Keep it in a cool, dry place where the temperature stays below 25°C. |

For more information, see Section [5. What should I know while taking GENOX?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some may be minor and temporary. However, some side effects may be serious. Tell your doctor immediately if you have a skin rash, itching, hives or peeling skin, 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. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking GENOX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking GENOX.**

Where to find information in this leaflet:

1. [Why am I taking GENOX?](#)
2. [What should I know before I take GENOX?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take GENOX?](#)
5. [What should I know while taking GENOX?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking GENOX?

GENOX contains the active ingredient tamoxifen citrate.

GENOX blocks the actions of estrogen. Estrogen is a natural female sex hormone. In some types of breast cancer, estrogen can help cancer cells to grow.

GENOX is used to either 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 gynecological 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 of 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.

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

Your doctor may prescribe this medicine for another use. GENOX is not addictive.

2. What should I know before I take GENOX?

Warnings

Do not take GENOX if:

- you are allergic to any 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:
 - o skin rash, itching or hives
 - o swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
 - o wheezing or shortness of breath.

Always check the ingredients to make sure you can use this medicine.

- 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)
- the expiry date printed on the pack has passed or the packaging is torn or shows signs of tampering.

Tell your doctor if you:

- have or have had any other medical conditions such as:
 - o a history of hereditary angioedema (as GENOX may cause or worsen symptoms of hereditary angioedema)
 - o any unusual or unexplained vaginal bleeding or discharge
 - o any blood disorder or problems such as thrombocytopenia or leucopenia
 - o liver problems
 - o deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs)
 - o any heart conditions including heart rhythm problems (arrhythmia). The risk of heart rhythm problems may be increased in such patients when using GENOX.
- take any medicines for any other condition
- are allergic to:
 - o tamoxifen, the active ingredient in GENOX
 - o any of the other ingredients in GENOX listed at the end of this leaflet
 - o other anti-estrogen medicines
 - o any other medicines
 - o any other medicines, foods, dyes or preservatives.

If you have an allergic reaction, you may experience a skin rash, hay fever, difficulty breathing or feel faint.

- have not been through menopause
- plan to become pregnant or breastfeed.

GENOX is not recommended for use in pregnancy and breastfeeding.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Men are recommended to use effective contraceptive measures and to not father a child while receiving tamoxifen and for six months following completion of treatment.

Do not take GENOX if you are breastfeeding.

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

Children

Do not give GENOX to children.

There is no experience of its use in children.

GENOX is not approved for use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 e.g. 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 or may not work as well. They could also cause side effects if you take them with GENOX.

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GENOX.

4. How do I take GENOX?

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

They may differ from the information contained in this leaflet.

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.

How to take GENOX

- **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 GENOX

- Keep taking GENOX for as long as your doctor recommends.

If you forget to take GENOX

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 use too much GENOX

If you think that you or anyone else has taken too much GENOX, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while taking GENOX?

Things you should do

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking GENOX
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking GENOX
- If you go into hospital, please let the medical staff know that you are taking GENOX
- Visit your doctor regularly so they can check on your progress.

You will need to have regular gynecological 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.

Call your doctor straight away if you:

- notice any unusual gynecological symptoms, especially vaginal bleeding or discharge, even if it occurs after the 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.

Things you should not do

- For women: do not get pregnant while you are taking GENOX and for nine months after you stop taking GENOX.
- For Men: do not father a child while you are taking GENOX and for six months after you stop taking GENOX.
- Ask your doctor about reliable methods of contraception.
- 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 stop taking GENOX, or lower the dosage, unless you have discussed this with your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take GENOX if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GENOX affects you.

Some patients may experience dizziness, fatigue or light headedness. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep your GENOX tablets in the blister pack until it is time to take them. If you take GENOX out of the blister pack it will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some people, such as those who have not had menopause, may have a greater risk of getting some of these side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

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

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • depression • hot flushes • nausea and vomiting • unusual vaginal discharge • any change in your periods • itching around the vagina • diarrhoea or constipation • headache, dizziness or light headedness • hair thinning or hair loss • leg cramps | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> 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 | <p>Speak to your doctor immediately if you notice any of these side effects.</p> |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> rash, itching, 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. | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

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 an unusual vaginal bleeding or other gynecological 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.

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

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What GENOX contains

| | |
|--|---|
| Active ingredient (main ingredient) | tamoxifen citrate 10 mg or 20 mg per tablet |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> mannitol maize starch croscarmellose sodium magnesium stearate |

The tablets are gluten free.

Do not take this medicine if you are allergic to any of these ingredients.

What GENOX looks like

- GENOX 10** - round, white tablet marked "TN" over "10" on one side and "G" on the other side. (AUST R 40063)
- GENOX 20** - round, white, scored tablet marked "TN" over "20" on one side and "G" on the other side (AUST R 40065)

Each pack contains 30 or 60 tablets.

Who distributes GENOX

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

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