

Genox

contains the active ingredient tamoxifen (as citrate)

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.

Genox contains the active ingredient tamoxifen, which works by blocking the actions of oestrogen, a female sex hormone.

The exact way in which Genox works against breast cancer cells is not exactly known, however it may be related to the way it blocks oestrogen in the body.

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 two months after you have stopped treatment with it.

Do not take Genox if you are breastfeeding.

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

Do not take Genox if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Genox if the packaging shows signs of tampering or the tablets do not look quite right.

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

Before you start to take it

Tell your doctor if you are allergic to 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:

- liver problems
- any blood disorder or problems such as thrombocytopenia or leucopenia
- unusual or unexplained vaginal bleeding or discharge.

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:

- other medicines used to treat cancer
- medicines used to prevent blood clots such as warfarin
- rifampicin, an antibiotic.

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.

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 Genox

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 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.

How long to take Genox for

Keep taking Genox for as long as your doctor recommends.

If you take too much Genox (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think 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

Before starting any new medicine, tell your doctor or pharmacist that you are taking Genox.

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

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

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 use Genox to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

Genox may cause dizziness, lightheadedness 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 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:

- hot flushes
- nausea, vomiting
- changes in your period
- headache
- dizziness or lightheadedness
- hair loss or thinning
- itching around the genital area.

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

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

- any changes in vision
- unusual vaginal bleeding or discharge, pelvic pain or pressure
- pain in the bones or at the site of your cancer
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and eyes, dark coloured urine
- severe upper stomach pain with nausea and vomiting
- swelling of hands, ankles, feet or lower leg.

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:

- sharp, stabbing pain or swelling in the groin, chest or leg

- coughing up blood, sudden shortness of breath
- symptoms of high calcium levels in the blood such as loss of appetite, thirst, nausea, vomiting, constipation and stomach pain, sometimes together with confusion and muscle weakness
- severe blisters, or bleeding in the lips, eyes, nose, mouth or genitals
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

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 degrees 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 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 Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration numbers:

Genox 10 - AUST R 40063

Genox 20 - AUST R 40065

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