

NOLVADEX®

Tamoxifen citrate

Consumer Medicine Information

What is in this leaflet

In this leaflet, NOLVADEX means Nolvadex or Nolvadex-D tablets.

This leaflet answers some of the common questions people ask about NOLVADEX. It does not contain all the information that is known about NOLVADEX.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking NOLVADEX against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NOLVADEX is for

NOLVADEX 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 NOLVADEX for reducing the risk of breast cancer occurring, your knowledge of treatment risks becomes more important because you don't currently have breast cancer. NOLVADEX 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. NOLVADEX 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 NOLVADEX reduces, but does not eliminate, the risk of breast cancer.

NOLVADEX blocks the actions of oestrogen. Oestrogen is a natural female sex hormone. In some types of breast cancer, oestrogen can help cancer cells to grow.

Your doctor will have explained why you are being treated with NOLVADEX and told you what dose to take.

Follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

NOLVADEX is not addictive.

Before you use NOLVADEX

When you must not use it

Do not use NOLVADEX if you are pregnant, trying to become pregnant or are breastfeeding. We do not know if it is safe for you to take it while you are pregnant. It may affect your baby if you take it at any time during pregnancy.

Your baby may take in NOLVADEX from breast milk if you are breastfeeding.

Do not use NOLVADEX if you are allergic to tamoxifen or any of the other ingredients in NOLVADEX.

Do not use NOLVADEX 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 NOLVADEX to children.

There is no experience of its use in children.

Do not take after the use by (expiry) date printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not take NOLVADEX if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

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

Before you start to use it

You must tell your doctor if:

1. you have any allergies to:

- tamoxifen, the active ingredient in NOLVADEX
- any of the other ingredients in NOLVADEX listed at the end of this leaflet
- other anti-oestrogen medicines
- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

2. you have or have ever had any of these medical conditions:

- a history of hereditary angioedema (as NOLVADEX may cause or worsen symptoms of hereditary angioedema).
- any unexplained vaginal bleeding
- problems with your blood
- liver problems
- deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs).
- any heart conditions including heart rhythm problems (arrhythmia). The risk of heart rhythm problems may be increased in such patients when using NOLVADEX.

It may not be safe for you to take NOLVADEX if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- oral contraceptives ('the pill')

- hormone replacement therapy
- medicines used to thin your blood e.g. warfarin
- rifampicin
- chemotherapy
- any medicines that you buy at the chemist, supermarket or health food shop.

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

These medicines may affect the way NOLVADEX works or may not work as well. They could also cause side effects if you take them with NOLVADEX.

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

If you have not told your doctor about any of these things, tell them before you take any NOLVADEX.

Taking NOLVADEX

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day.

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

How much to take

Your doctor will decide how much NOLVADEX you need to take.

The usual dose is 20 mg of NOLVADEX each day.

This is two 10 mg Nolvadex tablets taken together or one 20 mg Nolvadex-D tablet taken once a day.

Some people need to take 40 mg once a day. Your doctor will tell you if this is necessary.

Swallow your NOLVADEX whole, with a full glass of water. Do not chew or crush the tablets.

When to take it

Take NOLVADEX at about the same time each day.

It does not matter if you take NOLVADEX before, with or after food.

How long to take it

Continue taking NOLVADEX for as long as your doctor or pharmacist tells you to.

If you forget to take it

If you miss a dose, take it as soon as you remember, as long as it is 12 hours before the next dose is due.

If it is less than 12 hours to the next dose, do not take the dose you have missed.

Do not double the dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

Overdose

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much NOLVADEX. Do this even if there are no signs of discomfort or poisoning.

If you take too much NOLVADEX you may experience problems with the rhythm of your heart.

While you are using it

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking NOLVADEX.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NOLVADEX.

If you go into hospital, please let the medical staff know that you are taking NOLVADEX.

Things you must not do

Do not get pregnant while you are taking NOLVADEX and for nine months after you stop taking NOLVADEX.

Ask your doctor about reliable methods of contraception.

Do not breastfeed while you are taking NOLVADEX.

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

Do not stop taking NOLVADEX, or lower the dosage, unless you have discussed this with your doctor.

Things to be careful of

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

Some patients may experience dizziness, fatigue or light headedness.

Side effects

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

NOLVADEX helps most people with breast cancer, but it may have

unwanted side effects in a few people.

All medicines can have side 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.

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

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 NOLVADEX 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.

NOLVADEX 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.

NOLVADEX may cause or worsen symptoms of hereditary angioedema.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen.

- 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. These symptoms could be signs of a stroke.

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

These are serious side effects. You may need urgent medical treatment.

Serious side effects are rare.

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

- 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

These are all mild side effects of NOLVADEX.

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 NOLVADEX.

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

Some people may get other effects while taking NOLVADEX.

After using it

Storage

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

If you take NOLVADEX out of the blister pack it will not keep well.

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

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.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What NOLVADEX looks like

Nolvadex 10 mg tablets are white to off-white, round film-coated tablets marked Nolvadex 10 on one side.

Nolvadex-D 20 mg tablets are white to off-white, octagonal (eight sided)

film-coated tablets marked Nolvadex-D on one side.

Ingredients

NOLVADEX contains tamoxifen as the active ingredient.

Nolvadex 10 mg tablets each contain 10 mg tamoxifen and Nolvadex-D 20 mg tablets each contain 20 mg of tamoxifen,

plus:

- maize starch
- lactose monohydrate
- croscarmellose sodium
- gelatin
- magnesium stearate (572)
- hypromellose (464)
- macrogol 300
- titanium dioxide (171)

Each pack of NOLVADEX tablets contains 30 tablets in blister strips.

NOLVADEX does not contain added sucrose, gluten, tartrazine or any other azo dyes.

Distributor

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805342

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Nolvadex 10 mg tablets

AUST R 11233

Nolvadex-D 20 mg tablets

AUST R 11232

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