

Package leaflet: Information for the patient
Nolvadex® and Nolvadex® D
tamoxifen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Nolvadex and Nolvadex D will be referred to as Nolvadex throughout this leaflet.

What is in this leaflet:

1. What Nolvadex is and what it is used for
2. What you need to know before you take Nolvadex
3. How to take Nolvadex
4. Possible side effects
5. How to store Nolvadex
6. Contents of the pack and other information

1. What Nolvadex is and what it is used for

What Nolvadex is

The name of your medicine is Nolvadex. Nolvadex contains a medicine called tamoxifen, which belongs to a group of medicines called ‘anti-oestrogens’.

What Nolvadex is used for

- Nolvadex is used to treat breast cancer.
- Nolvadex can also be used to treat infertility in women caused by a failure to produce and release eggs (ovulate) properly.
- Nolvadex can also reduce the risk of developing breast cancer occurring in those women who have an increased likelihood of developing breast cancer (your risk). It is important that your healthcare professional calculates your risk of developing breast cancer and discusses the result with you before commencing treatment. There are a number of specific tools available to calculate breast cancer risk, based on information such as your age, family history, genetics, reproductive factors (e.g. age when periods started and stopped, had children or not, taken or taking hormonal replacement therapy and/or oral contraceptive pill) and history of breast disease. Although the tools can estimate your risk, it doesn't mean you will get breast cancer, being at increased risk means you have a higher chance of developing breast cancer. If you and your healthcare professional are considering using Nolvadex for this, it is important to understand the benefits as well as the side effects of taking Nolvadex because you don't currently have breast cancer and Nolvadex reduces, but does not stop the risk of developing breast cancer.

If you want to know more about how to decide whether tamoxifen is right for you, there is more information for patients on the National Institute for Health and Care Excellence website. Ask your doctor to talk to you about the information which is available for patients.

How Nolvadex works

Oestrogen is a natural substance in your body known as a 'sex hormone'. Some breast cancers need oestrogen to grow and Nolvadex works by blocking the effects of oestrogen.

2. What you need to know before you take Nolvadex

Do not take Nolvadex:

- If you are pregnant or think you might be pregnant (see the section on 'Pregnancy' below).
- If you are allergic to tamoxifen or any of the other ingredients of this medicine (listed in section 6).
- If you are taking anastrozole.
- If you are taking any treatment for infertility.
- If you have had blood clots in the past and the doctor did not know what caused them.
- If someone in your family has had blood clots with the cause not known.
- If your doctor has told you that you have an illness which runs in the family that increases the risk of blood clots.
- If you are taking medicines used to prevent blood clots such as warfarin

Do not take Nolvadex if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Nolvadex.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nolvadex.

In delayed breast reconstruction operation (weeks to years after the primary breast operation when your own tissue is moved to shape a new breast), Nolvadex may increase the risk of the formation of blood clots in the small vessels of the tissue flap which may lead to complications.

Nolvadex therapy may be used to reduce the risk of breast cancer and it can be associated with serious side effects such as blood clots in the veins of your leg (deep vein thrombosis), blood clots in your lungs (pulmonary embolus) and uterine cancer, all of which can be fatal. Other less serious side effects such as hot flushes, vaginal discharge, menstrual irregularities and pelvis pain 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. All assessments with your healthcare professional of the potential benefits and risks prior to starting therapy are essential. You should understand that Nolvadex reduces, but does not eliminate the risk of breast cancer.

If you have or have had heart problems or an irregular heartbeat (arrhythmia), you may be at a higher risk of changes in your heart's electrical activity (known as QT prolongation) when using tamoxifen. QT prolongation can be seen on a heart test called an electrocardiogram (ECG) and may increase the risk of serious heart rhythm problems. If you are at an increased risk, your doctor should check your blood for important blood salts and minerals (electrolytes) and check your heart activity with an ECG before and during treatment with Nolvadex.

If you have a history of hereditary angioedema as Nolvadex may cause or worsen symptoms of hereditary angioedema. If you experience symptoms such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing, contact a doctor immediately.

Serious skin reactions

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Nolvadex treatment. Stop using Nolvadex and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children

This medicine is not for use in children.

Operations

If you are to undergo planned surgery, you should tell your doctor or pharmacist as they may wish to consider stopping your treatment for a short period.

Other medicines and Nolvadex

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Nolvadex can affect the way some other medicines work and some medicines can have an effect on Nolvadex.

In particular, tell your doctor or pharmacist if you are taking any other medicines:

- Oral contraceptives
- Hormone replacement therapy (HRT)
- Antidepressants (e.g. paroxetine, fluoxetine).
- Bupropion (used as an antidepressant or aid to smoking cessation).
- Quinidine (for example used in the treatment of cardiac arrhythmia).
- Cinacalcet/cinacalcet (for treatment of disorders of the parathyroid gland).
- Blood thinning medicines such as warfarin. These are known as 'anti-coagulants'
- Rifampicin which is used for tuberculosis (TB).
- Medicines known as 'aromatase inhibitors' that are used to treat breast cancer. These include anastrozole, letrozole and exemestane.
- Medicines that can affect your heart's electrical activity (known as QT prolonging medications). Taking these medicines with Nolvadex may increase the risk of heart rhythm problems. Some common examples include certain antibiotics (erythromycin, clarithromycin) and some antidepressants and antipsychotics.

Contraception

Women who can become pregnant should use adequate non-hormonal contraception (e.g., barrier contraception) during treatment with Nolvadex and for an additional nine months after stopping treatment.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

- Do not take Nolvadex if you are pregnant. This is because it may affect your unborn baby.
- Avoid becoming pregnant and breast feeding whilst taking Nolvadex and for nine months after stopping treatment.
- As you should not become pregnant when taking Nolvadex, please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by Nolvadex.
- You should see your doctor immediately if you think you may have become pregnant after starting to take Nolvadex.

Breast-feeding

Talk to your doctor before taking Nolvadex if you are breast-feeding.

Driving and using machines

Nolvadex is not likely to affect your ability to drive or use any tools or machines. However, tiredness has been reported with the use of Nolvadex and caution should be observed when driving or operating machinery while such symptoms persist.

Nolvadex tablets contain lactose, titanium dioxide and sodium

- Nolvadex tablets contain lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Nolvadex tablets contain titanium dioxide. This may cause a problem in a small number of people who are sensitive to this ingredient.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Nolvadex

Always take Nolvadex exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Breast cancer treatment

The recommended dose for breast cancer is 20 mg daily.

Infertility

The dose for infertility depends on your periods (menstrual cycle).

- If you are having regular periods, the recommended dose is one 20 mg tablet daily on the 2nd, 3rd, 4th and 5th days of your period.
- If this does not work, your doctor may suggest that you take a higher dose of Nolvadex during your next period. If this happens, the usual dose is 40 mg or 80 mg daily on the 2nd, 3rd, 4th and 5th days of your period.

- If you are not having regular periods, you can start taking the tablets on any day of the month.

Reducing the risk of breast cancer

The recommended dose for reducing the risk of breast cancer is 20 mg daily for 5 years. Your healthcare professional will calculate your risk of breast cancer occurring using information about you, your medical history and any family history of breast cancer.

If you take more Nolvadex than you should

If you take more Nolvadex than you should, talk to a doctor or pharmacist straight away.

If you forget to take Nolvadex

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Nolvadex and tell your doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

- Symptoms of a blood clot. These include swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak.
- Symptoms of a stroke. These include sudden onset of the following: weakness or paralysis of the arms or legs, being unable to move the arms or legs, sudden difficulty speaking, walking, or holding things, or difficulty thinking. These symptoms are caused by a reduced blood supply in the brain.
- Difficulty in breathing.
- Swelling of the face, lips, tongue or throat which may make it difficult to swallow.
- Swelling of the hands, feet or ankles.
- Nettle rash (also called ‘hives’ or ‘urticaria’).
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome, toxic epidermal necrolysis] – these side effects occur rarely.
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Nolvadex may cause or worsen symptoms of hereditary angioedema.

Tell your doctor straight away if you notice any of the following:

- Unusual bleeding from your vagina.
- Irregular periods, especially if associated with heavier bleeding as this could be a warning sign for a certain type of cancer affecting the lining of your womb (endometrial cancer).
- Vaginal discharge.
- A feeling of discomfort in the lower tummy (pelvis) such as pain or pressure.

These effects may mean that there have been changes to the lining of your womb (the endometrium). Sometimes these effects are serious and could include cancer. They can happen during or after treatment with Nolvadex.

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Nausea.
- Fluid retention.
- Skin rash.
- Hot flushes.
- Tiredness.
- Depression

Common (may affect up to 1 in 10 people)

- Anaemia (a blood problem which means you have too few red blood cells).
- Changes in vision due to cataracts or changes to the retina of your eye.
- Increased amounts of fats in your blood (shown by blood tests).
- Allergic reactions.
- Leg cramp.
- Changes in the womb (including changes to its lining and benign growths).
- Headache.
- Feeling light-headed.
- Itching of the genitals.
- Thinning of the hair.
- Vomiting.
- Diarrhoea.
- Constipation.
- Changes in blood tests of liver function.
- Formation of fatty liver cells.
- Muscle pain.
- Sensory changes (including taste disorder and numbness or tingling in the skin).
- Increased risk of blood clots (including clots in small vessels).

Uncommon (may affect up to 1 in 100 people)

- Blood problems. This can make you bruise more easily, get serious infections, or feel very tired or breathless.
- Changes to your vision and difficulty seeing.
- Swelling of the pancreas. This may cause moderate to severe pain in the stomach.
- Changes in the amount of calcium in your blood. The signs may include feeling very sick, being sick a lot or being thirsty. **Tell your doctor if this happens** because he or she may want you to have blood tests.
- Inflammation of the lungs. The symptoms may be like pneumonia (such as feeling short of breath and coughing).
- Liver cirrhosis (problems with your liver).

Rare (may affect up to 1 in 1,000 people)

- Severe blood problems. This can make you bruise more easily, get serious infections, or feel very tired or breathless.
- Changes to the cornea of your eye.
- Problems with the nerve that connects your retina to your brain.
- Swelling of the optic nerve.
- On occasions more severe liver diseases have occurred from which some patients have died. These liver diseases include inflammation of the liver, liver cirrhosis, liver cell damage, reduced bile formation, and failure of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes).
- Damage to blood vessels causing red or purple dots in the skin.
- Severe skin disorder. The symptoms include redness, blistering and peeling.
- Cells normally only found in the lining of the womb found elsewhere in your body, cysts on the ovaries, and cancer (the signs of this are given above).
- Non-cancerous mass in the inner lining of the vagina (called vaginal polyp).
- At the beginning of treatment, a worsening of the symptoms of your breast cancer such as an increase in pain and/or an increase in the size of the affected tissue may occur (known as tumour flare).
- Changes in the electrical activity of the heart (ECG QT prolonged).

Very rare (may affect up to 1 in 10,000 people)

- Inflammation of the skin characterized by rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus).
- A skin condition characterised by skin blisters in areas exposed to the light, this is due to the increased liver production of a special group of cell pigments (called porphyrins).
- Radiation recall - skin rash involving redness, swelling, and/or blistering (like severe sunburn) of the skin after receiving radiation therapy.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nolvadex

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store your tablets in the original package. Keep the blister strip in the carton. This will protect your medicine from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nolvadex Contains

The active substance is tamoxifen.

Each Nolvadex 10 mg tablet contains Tamoxifen Citrate Ph. Eur. 15.2 mg equivalent to 10 mg tamoxifen.

Each Nolvadex D 20 mg tablet contains Tamoxifen Citrate Ph. Eur. 30.4 mg equivalent to 20 mg Tamoxifen.

The other ingredients are croscarmellose sodium, gelatin, lactose, macrogol, magnesium stearate, maize starch, methylhydroxypropylcellulose and titanium dioxide.

What Nolvadex looks like and contents of the pack

Nolvadex 10 mg Tablets are white to off-white, round, biconvex, film-coated tablets, with markings on one face and plain on the reverse. They come in packs (blister strips or bottles) of 30 or 250 tablets.

Nolvadex D 20 mg tablets are octagonal, white film-coated tablets. They are marked Nolvadex D on one side. They come in packs of 30 or 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Nolvadex and Nolvadex D are held by AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge, CB2 0AA, UK.

Nolvadex and Nolvadex D are manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Nolvadex	17901/0033
Nolvadex D	17901/0034

This is a service provided by the Royal National Institute of Blind People.

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