

# NOLVADEX-D TABLET

Tamoxifen (20mg)

---

## What is in this leaflet

1. What Nolvadex-D Tablet  
Tablet is used for
2. How Nolvadex-D Tablet  
works
3. Before you use Nolvadex-  
D Tablet
4. How to use Nolvadex-D  
Tablet
5. While you are using it
6. Side effects
7. Storage & Disposal of  
Nolvadex-D Tablet
8. Product Description
9. Manufacturer and Product  
Registration Holder
10. Date of Revision

## What Nolvadex-D Tablet is used for

Nolvadex-D Tablet is used to treat breast cancer.

## How Nolvadex-D Tablet works

Nolvadex-D Tablet contains a medicine called tamoxifen. This belongs to a group of medicines called 'anti-oestrogens'. Oestrogen is a natural substance in your body known as a 'sex hormone'. Nolvadex-D Tablet works by blocking the effects of oestrogen.

## Before you use Nolvadex-D Tablet

### When you must not use it

Do not use Nolvadex-D Tablet

- if you are allergic to tamoxifen or any of the ingredients in Nolvadex-D Tablet.
- if you are pregnant, are trying to become pregnant or are breastfeeding.

Nolvadex-D Tablet should not be given to children.

### Before you start to use it

Take special care with Nolvadex-D Tablet

- on what contraceptive precautions you should take, as some may be affected by Nolvadex-D Tablet. Please see your doctor for advice.
- if you have any unusual vaginal bleeding or other gynaecological symptoms (such as pelvic pain or pressure) when you are taking Nolvadex-D Tablet or anytime afterwards. This is because a number of changes to the lining of the womb (the endometrium) may occur, some of which may be serious and could include cancer.
- if you go into hospital. Let the medical staff know you are taking Nolvadex-D Tablet.
- 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-D Tablet may increase the risk of the formation of blood clots in the small vessels of the tissue flap which may lead to complications.

### Taking other medicines

Please inform your doctor if you are taking, or have recently taken any other medicines, even those you have bought without prescription. In particular, you should inform your doctor if you are taking anti-coagulants such as warfarin (to prevent blood clots) and antidepressants such as paroxetine (to improve mood or symptoms of hot flushes), rifampicin (antibiotic)

and cytotoxic agents, for the treatment of breast cancer. Nolvadex-D Tablet should not be taken with aromatase inhibitors, such as anastrozole, letrozole or exemestane.

## How to use Nolvadex-D Tablet

### How much to use

- Follow your doctor's instructions about when and how to take your tablets. Please read the label. Ask your doctor or pharmacist if you are not sure.
- The usual dose is 20 mg to 40 mg daily.

### When to use it

- Nolvadex-D Tablet is normally taken once or twice a day.
- Swallow the tablets whole with a drink of water.
- Try to take your medicine at the same time each day.
- Do not stop taking your tablets unless your doctor tells you to stop even if you are feeling well.

### How long to use it

Take Nolvadex-D Tablet as directed by your Healthcare provider.

### If you forget to use it

Take the dose as soon as you remember. Do not take two doses at the same time.

### If you use too much (overdose)

If you take more than your normal dose, contact your doctor or go to the nearest hospital.

## While you are using it

### Things you must do

It is important to keep taking Nolvadex-D Tablet every day

and as your doctor has told you to. The instructions on the label should remind you of what the doctor has said.

Things you must not do

Do not stop taking your dose without talking to your Healthcare provider.

Things to be careful of

*Pregnancy and breast-feeding*

You should not become pregnant or breast-feed when taking Nolvadex-D Tablet or during the two months after you stop taking it.

*Driving and using machines*

Nolvadex-D Tablet tablets are unlikely to affect your ability to drive a car or to operate machinery. However, tiredness has been reported with the use of NOLVADEX and caution should be observed when driving or operating machinery while such symptoms persist.

**Side effects**

Like all medicines, Nolvadex-D Tablet can have side effects. Tell your doctor as soon as possible if any of the following side effects bothers you or continues:

- Hot flushes
- Vaginal bleeding
- Changes on the endometrium (lining of the womb), which may also be seen as unusual vaginal bleeding
- Uterine fibroids (growth at the lining of the womb), which may also be symptoms such as discomfort in the pelvis or as vaginal bleeding.
- Cancer in the endometrium or uterus (the womb).
- Itching around the vagina
- Vaginal discharge
- Stomach upsets (including nausea, vomiting, diarrhoea, and constipation)

- Headaches
- Light-headedness
- Sensory changes (including taste disorder and numbness or tingling in the skin)
- Fluid retention (possibly seen as swollen ankles)
- Low platelet counts (thrombocytopenia)
- Low white cell counts (leucopenia) or isolated decrease of specific white cells (neutropenia and agranulocytosis)
- Decrease in red blood cells (anaemia)
- Hypertriglyceridemia (increased levels of fats in the blood) sometimes with pancreatitis (pain or tenderness in your upper abdomen)
- Skin rash or itching or peeling skin
- Inflammation of small blood vessels in the skin leading to skin rash
- Hair loss
- Changes in blood tests of liver function. On occasions, more severe liver diseases have occurred from which some patients have died. These liver diseases include inflammation of the liver, liver scarring, liver cell damage, formation of fatty liver cells, 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 whites of eyes).
- 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
- Difficulties in seeing properly possibly due to cataracts (the lens of the eye becoming progressively opaque, resulting in blurred vision), changes to the cornea or disease of the retina
- Ovarian cysts (fluid-filled sacs or pockets within or on the surface of an ovary)
- Increased risk of blood clots (including clots in small vessels)
- Inflammation of the lungs, which may present with the same symptoms as pneumonia, such as breathlessness and cough.
- Leg cramps
- Muscle pain
- Non-cancerous mass in the inner lining of the vagina (called vaginal polyp)
- Inflammation of the skin characterized by rash or skin-redness, 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 production of a special group of cell pigments (called porphyrins) in the liver
- 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. If you experience excessive nausea, vomiting and thirst, you should tell your doctor. This may indicate possible changes in the amount of calcium in your blood and your doctor may have to do certain blood tests.
- Tiredness
- Radiation recall - skin rash involving redness, swelling, and/or blistering of the skin after receiving radiation therapy

Do not be alarmed by this list of possible events. You may not have any of them.

Tell your doctor or pharmacist if you think you have any of these or any other problems with your tablets.

Stop taking Nolvadex-D Tablet and contact your doctor immediately in any of the following situations:

- If you develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat.
- If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty swallowing
- If you develop swelling of the hands, feet or ankles
- If you develop urticaria (nettle rash or hives)

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

### **Storage and Disposal of Nolvadex-D Tablet**

#### Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C
- Keep your tablets in the container.

#### Disposal

- If your doctor decides to stop your treatment, dispose your tablets in an appropriate way.
- Do not take your tablets after the expiry date on the container. Dispose of them in an appropriate way.
- Medicines should not be disposed of via wastewater or household waste. Ask

your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **Product Description**

#### What it looks like

White to off-white, octagonal, biconvex, film coated tablets, intagliated on one face with NOLVADEX-D and plain on the reverse.

Nolvadex-D Tablet tablets come in blister packs containing 30 tablets.

#### Ingredients

- Active ingredient:  
The active substance is tamoxifen.
- Inactive ingredients:  
The other ingredients are croscarmellose sodium, gelatin, lactose monohydrate, macrogol 300, magnesium stearate, maize starch, hypromellose, titanium dioxide.

#### MAL number:

MAL19870703ARZ

### **Manufacturer**

AstraZeneca UK Limited,  
Macclesfield, Cheshire, United Kingdom

### **Product Registration Holder**

AstraZeneca Sdn. Bhd.  
Level 12, Surian Tower,  
1 Jalan PJU 7/3,  
Mutiara Damansara,  
47810 Petaling Jaya,  
Malaysia

### **Date of revision**

19/04/2016

Doc ID-002080671 V4 (based on PI: Doc ID-002080577 V5)

### **Serial Number:**

BPFK(4/2)070416/00102