Package leaflet: Information for the patient
Nolvadex® D 20 mg Film-coated Tablets
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.

What is in this leaflet:

1. What Nolvadex D is and what it is used for

The name of your medicine is 'Nolvadex D 20 mg Film-coated Tablets' (called Nolvadex D in this leaflet). Nolvadex D 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 works by blocking the effects of oestrogen.

Nolvadex D is used to treat breast cancer.

2. What you need to know before you take Nolvadex D

Do not take Nolvadex D:
- 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 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.

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

Warnings and precautions
If you have menstrual periods, these may stop whilst taking Nolvadex D.

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 may increase the risk of the formation of blood clots in the small vessels of the tissue flap which may lead to complications.

Talk to your doctor or pharmacist before you take Nolvadex D if you have a history of hereditary angioedema as Nolvadex D 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 including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Nolvadex D treatment. Stop using Nolvadex D 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 going to have an operation (including planned surgery), tell your doctor or pharmacist. They may suggest that you stop taking Nolvadex D for a short time.

Other medicines and Nolvadex D
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Nolvadex D can affect the way some medicines work and some medicines can have an effect on Nolvadex D.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Medicines such as warfarin that are used to thin your blood. 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.
- Paroxetine, fluoxetine (e.g. antidepressants).
- Bupropion (antidepressant or aid to smoking cessation).
- Quinidine (for example used in the treatment of cardiac arrhythmia).
- Cincalet/cinacalcet (for treatment of disorders of the parathyroid gland).

Pregnancy and breast-feeding

<u>Pregnancy</u>
- Do not take Nolvadex D if you are pregnant. This is because it may affect your unborn baby.
- Do not become pregnant while taking Nolvadex D and for nine months after you stop taking it. Ask your doctor for advice on what contraceptive to use - Nolvadex D affects how well some contraceptives work.
- If you are taking Nolvadex D and you think you have become pregnant, tell your doctor straight away.

<u>Breast-feeding</u>

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

Driving and using machines
Nolvadex D is not likely to affect your ability to drive or use 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 D contains lactose
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 D contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Nolvadex D

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

Breast cancer
The recommended dose for breast cancer is one 20 mg tablet daily or as otherwise recommended by your doctor or pharmacist.

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

If you forget to take Nolvadex D
- 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 D 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 of the arms or legs, being unable to move the arms or legs, 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, difficulty in swallowing or breathing (angioedema). Nolvadex D may cause or worsen symptoms of hereditary angioedema.
- 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.

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

- Unusual bleeding from your vagina.
- 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 D.

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).

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 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Nolvadex D

- 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 and blister pack. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep the blister pack in the carton to protect the tablets from light.
- 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 D Tablets contain
The active substance is tamoxifen. Nolvadex D is produced as film-coated tablets which contain 20 mg of tamoxifen (as tamoxifen citrate).
The other ingredients are croscarmellose sodium, gelatin, lactose monohydrate, macrogol 300, magnesium stearate, maize starch, hypromellose and titanium dioxide. See section 2 ‘Nolvadex D contains lactose’ and ‘Nolvadex D contains sodium’ for more information.

What Nolvadex D Tablets look like and contents of the pack
Nolvadex D 20 mg Film-coated Tablets are octagonal, white film-coated tablets. They are marked ‘Nolvadex D’ on one side and plain on the other side. They are produced in blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder for Nolvadex D 20 mg Film-coated Tablets marketed in Ireland and Malta is AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Nolvadex D 20 mg Film-coated Tablets are manufactured by AstraZeneca AB, Gärtunavägen,

Södertälje 152 57, Sweden.

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