

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

**NOLVADEX®-D 20 mg Film-coated table
(Tamoxifen)**

Contains sugar lactose monohydrate 234 mg

Read all of this leaflet carefully before you start taking NOLVADEX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NOLVADEX-D has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

The content listing would normally reflect the six main sections of the leaflet

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

1. What NOLVADEX-D is and what it is used for

Each tablet of NOLVADEX -D contains 20 mg of tamoxifen.

NOLVADEX-D is used to treat breast cancer.

In the tumour of breast cancer patients, NOLVADEX-D prevents the female sex hormone, oestrogen, from binding to the oestrogen receptor, which has an effect on the growth of breast cancer.

2. What you need to know before you take NOLVADEX-D

Do not take NOLVADEX-D

- If you are hypersensitive (allergic) to tamoxifen or any other ingredients of NOLVADEX-D.
- If you are pregnant, are trying to become pregnant or are breastfeeding.
- NOLVADEX-D should not be given to children

Warnings and precautions

Take special care with NOLVADEX-D

- As to what contraceptive precautions you should take, as some contraceptive may be affected by NOLVADEX-D. 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 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.
- 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.
- 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.

Pregnancy and breastfeeding and fertility

- If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.
- Do not use NOLVADEX-D if you are pregnant, trying to become pregnant or are breastfeeding.
- You should not become pregnant or breast-feed when taking NOLVADEX-D and for nine months after you stop taking it.
- Please consult your doctor, pharmacist or other healthcare professionals for contraception advice

Driving and using machinery:

- NOLVADEX-D tablets are unlikely to affect your ability to drive a car or to operate machinery.

Other medicines with NOLVADEX-D:

- If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of NOLVADEX-D with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other health care professional for advice.

Please inform your doctor, pharmacist or other health care professional if you are taking or are about to stop taking medicines for:

- Cancer (cytotoxic agents)
- Tuberculosis (such as rifampicin)
- Preventing blood clots (anticoagulants)
- Improving mood or symptoms of hot flushes (antidepressants)

NOLVADEX-D contains lactose.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take NOLVADEX-D.

3. How to take NOLVADEX-D

- Always take NOLVADEX-D exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- The usual dose is 20 mg to 40 mg daily.
- NOLVADEX-D is normally taken once or twice a day.
- Try to take your medicine at the same time each day.
- If you have the impression that the effect of NOLVADEX-D is too strong or too weak, talk to your doctor or pharmacist.
- Do not share your medicines prescribed for you with any other person.
- Do not stop taking your tablets even if you are feeling better, unless your doctor tells you to.

If you take more NOLVADEX-D than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take NOLVADEX-D

If you miss a dose, take the dose as soon as you remember, but do not take your next dose at the same time. Then go on as before.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NOLVADEX-D can have side effects.

Not all side-effects reported for NOLVADEX-D are included in this leaflet. Should your general health worsen while taking NOLVADEX-D, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking NOLVADEX-D and tell your doctor immediately or go to the casualty department at your nearest hospital.

Tell your doctor if any of the following side effects bothers you.

Frequent side effects:

- Nausea
- Fluid retention (possibly seen as swollen ankles)
- Vaginal bleeding
- Vaginal discharge
- Hot flushes
- Depression (persistent sadness, despair, or hopelessness)

Less frequent side effects:

- Difficulties in seeing properly possibly due to cataracts or disease of the retina.
- Hypersensitivity reactions
- Leg cramps
- Muscle pain
- Increased risk of blood clots (including clots in small vessels)
- Fibroids (causes enlargement of the womb), which may also be seen as discomfort in the pelvis or as vaginal bleeding.
- Heart problems

- Headaches
- Light-headedness
- Sensory changes (including taste disorder and numbness or tingling in seen as vaginal bleeding)
- Hair loss
- Stomach upsets (including vomiting, diarrhoea and constipation)
- 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 cirrhosis, 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 eyes).
- Thrombocytopenia (bruising more easily)
- Disturbances of vision
- Pancreatitis (pain or tenderness in your upper abdomen), mostly in patients with increased levels of fat in the blood before treatment with NOLVADEX-D
- 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
- Cancer in the endometrium (lining of the womb).
- Inflammation of the lungs that may present with the same symptoms as pneumonia, such as breathlessness and cough
- Changes to the cornea of the eye
- Cases of optic nerve diseases have been reported in patients receiving tamoxifen and, in a small number of cases, blindness has occurred
- Cancer in the uterus (the womb)
- Non-cancerous mass in the inner lining of the vagina (called vaginal polyps)
- Ovarian cysts
- 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.

- Presence of tissue similar to the lining of the uterus at other sites in the pelvis (endometriosis).
- Certain liver problems such as inflammation of the liver (hepatitis)
- Itching or peeling skin
- Inflammation of small blood vessels in the skin leading to skin rash (cutaneous vasculitis)
- Inflammation of the skin characterised by rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus)
- A skin condition characterized by skin blisters in areas exposed to the skin condition characterized by skin blisters in areas exposed to the pigments (called porphyrins)
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema).
NOLVADEX may cause or worsen symptoms of hereditary angioedema.

The following side effects can also occur with NOLVADEX-D, and they are seen when a blood test is taken:

- Decrease in the number of platelets in the blood, resulting in bruising more easily.
- Decrease in the amount of white blood cells (leucopenia) or isolated decrease of specific white cells (neutropenia and agranulocytosis)
- Decrease in the quantity of oxygen-carrying pigment, haemoglobin in the blood
- Changes in the amount of liver enzymes
- Increased levels of fat in the blood.
- Decrease in red blood cells (anaemia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects you can help provide more information on the safety of NOLVADEX-D.

5. How to store NOLVADEX-D

Store at or below 25 °C

Store all medicines out of reach of children.

Keep blister in a carton until required for use.

Do not use NOLVADEX-D after the expiry date stated on the container

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NOLVADEX-D contains

The active substance is tamoxifen. NOLVADEX-D tablets contain 20 mg of tamoxifen as tamoxifen citrate 30,4 mg.

The other ingredients are: Croscarmellose sodium, gelatine, lactose monohydrate, macrogol 300, magnesium stearate, maize starch, methylhydroxypropylcellulose and titanium dioxide.

What NOLVADEX-D looks like and contents of the pack

NOLVADEX-D tablets are octagonal, white, film-coated tablets impressed with NOLVADEX-D on one face and may have a logo on the other.

NOLVADEX-D tablets are packed into blister strips of 30 tablets that are placed into cartons.

Holder of certificate of registration

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