

INFORMATION FOR THE CONSUMER

[Pr] NOLVADEX[®] - D

(tamoxifen citrate)

Tablets 20 mg

DESCRIPTION

NOLVADEX-D (tamoxifen citrate) is a medicine that blocks the effects of the hormone estrogen in the body. It is used to treat breast cancer.

The exact way that tamoxifen works against cancer is not known, but it may be related to the way it blocks the effects of estrogen on the body.

NOLVADEX-D is available only with your doctor's prescription.

WHAT DOES NOLVADEX-D CONTAIN?

In addition to the active ingredient tamoxifen citrate, each tablet contains the following inactive ingredients: lactose, corn starch, gelatin, croscarmellose sodium, magnesium stearate, methylhydroxy propylcellulose, macrogol 300 and titanium dioxide.

BEFORE USING THIS MEDICATION

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make.

Before taking NOLVADEX-D, tell your doctor if any of the following apply to you:

- If you have ever had any unusual or allergic reaction to NOLVADEX-D or to any one of its ingredients (See What Does NOLVADEX-D Contain?).
- If you intend to become pregnant. It is best to use some kind of birth control while you are taking NOLVADEX-D and for about two months after you stop taking it. Please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by NOLVADEX-D. Tell your doctor right away if you think you have become pregnant while taking tamoxifen or within two months of having stopped it.
- It is important that you tell your doctor immediately 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 are breastfeeding or intend to breastfeed.

- If you are taking or have recently taken any other prescription, including antidepressants such as paroxetine (to improve mood or symptoms of hot flashes), or over-the-counter medicine.
- If you have any other medical problems, especially cataracts (or other eye problems) or low blood cell counts.
- If you have a history of blood clots, including deep vein thrombosis (a blood clot in one of the deep veins of the body – usually within the leg) or are taking anticoagulants such as warfarin (to prevent blood clots).
- NOLVADEX-D should not be taken with aromatase inhibitors, such as anastrozole, letrozole or exemestane.
- If you are going to have a breast reconstruction operation where your own tissue is moved to shape a new breast and this occurs weeks to years after the primary cancer operation, NOLVADEX-D may increase your risk of complications, including complete loss of the new tissue.
- If you have a history of pulmonary embolism (obstruction of a pulmonary artery by foreign matter such as fat, air, tumour tissue or a blood clot).
- If you have a history of stroke.
- If you go into the hospital, let medical staff know you are taking NOLVADEX-D.

YOU SHOULD NOT TAKE NOLVADEX-D IF:

- You have ever had any unusual or allergic reaction to NOLVADEX-D or to any one of its ingredients (See What Does NOLVADEX-D Contain?).
- You are pregnant.

NOLVADEX-D should not be given to children.

PROPER USE OF THIS MEDICATION

Use this medication only as directed by your doctor. Do not use more or less of it and do not use it more often than your doctor ordered. Taking too much may increase the chance of side effects, while taking too little may not improve your condition.

NOLVADEX-D sometimes causes nausea and vomiting. However, it may have to be taken for several weeks or months to be effective. Even if you begin to feel ill, *do not stop using this medicine without first checking with your doctor.* Ask your health care professional for ways to lessen these effects.

Missed dose - If you miss a dose, take the dose as soon as you remember. Do not take two doses at the same time.

TO STORE THIS MEDICINE

- KEEP OUT OF THE REACH OF CHILDREN.
- Store at room temperature (15 to 30°C) and keep away from direct light.
- Do not store in damp places. Heat or moisture may cause the medicine to break down.
- Do not keep outdated medicine or medicine no longer needed.

PRECAUTIONS WHILE USING THIS MEDICINE

It is important to use some type of birth control while you are taking NOLVADEX-D. Please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by NOLVADEX-D. Tell your doctor right away if you think you have become pregnant while taking this medicine or within two months of stopping it.

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

SIDE EFFECTS OF THIS MEDICINE

Along with its needed effects, a medicine may cause some unwanted effects. Some side effects will have signs or symptoms that you can see or feel. Your doctor will watch for others by doing certain tests.

Also, because of the way this medicine acts on the body, there is a chance that it might cause other unwanted effects that may not occur until months or years after the medicine is used. NOLVADEX-D has been reported to increase the risk of cancer of the endometrium or uterus (womb) as well as uterine fibroids (non-cancerous tumours) in some women taking it. It may also cause a drop in some of your blood cell counts, thrombocytopenia (bruising), an increased risk of blood clots and stroke, hypertriglyceridemia, pancreatitis, jaundice and ovarian cysts. In addition, NOLVADEX-D has been reported to cause cataracts and other eye problems. Discuss these possible effects with your doctor.

Check with your doctor or pharmacist as soon as possible if any of the following side effects occur:

- Hot flushes
- Discomfort in the pelvis

- Vaginal bleeding
- Itching around the vagina
- Vaginal discharge
- Stomach upsets (including nausea, vomiting, diarrhea 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 blood cell counts (leucopenia) or decrease of specific white cells (neutropenia and agranulocytosis)
- Decrease in red blood cells (anemia)
- Pain or tenderness in 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 occasion 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)
- Disturbances of vision or difficulties in seeing properly (possibly due to cataracts, change to the cornea or disease of the retina)
- Cases of optic nerve diseases have been reported and, in a small number of cases, blindness has occurred
- Breathlessness and cough (inflammation of the lungs)
- Pain, swelling or redness of the calf or leg which may indicate a blood clot

- Chest pain or shortness of breath which may indicate a blood clot
- 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 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 light, (a condition called porphyria cutanea tarda)
- Sudden onset of weakness or paralysis of the arms or legs, sudden difficulty walking or talking, 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 could be symptoms of a stroke)
- 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. In addition 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 and weakness
- A skin reaction involving redness, swelling, and/or blistering of the skin in areas previously exposed to radiation therapy (a condition called radiation recall).

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

STOP TAKING NOLVADEX 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 'nettle rash' or 'hives' (urticaria).**

If you need any further information ask your doctor or pharmacist.

Note: This Consumer Information Leaflet provides you with the most current information at the time of printing. For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at:

Customer Inquiries: 1-800-668-6000

Renseignements: 1-800-461-3787

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