Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr NOLVADEX®-D
tamoxifen citrate tablets

This Patient Medication Information is written for the person who will be taking **NOLVADEX-D**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **NOLVADEX-D**, talk to a healthcare professional.

Serious warnings and precautions box

- NOLVADEX-D was linked with serious and life-threatening events in a breast cancer prevention study. These included uterine cancer, stroke, blocked blood vessel in the lungs (pulmonary embolism), and blood clots forming in deep veins like the legs (deep vein thrombosis). These events were fatal in some patients. **NOLVADEX-D is not approved for the prevention of breast cancer in Canada.**

- The benefit of NOLVADEX-D outweighs the risks in most women who receive NOLVADEX-D for the treatment of their breast cancer. In Canada, NOLVADEX-D is approved for the treatment of breast cancer (see "What NOLVADEX-D is used for:").

- Talk to your healthcare professional if you have any questions about your treatment with NOLVADEX-D and any potential side effects.

What NOLVADEX-D is used for:

NOLVADEX-D is used in women to treat:

- Early-stage breast cancer after surgery, radiation or chemotherapy in patients with tumours that are estrogen receptor positive.
- Breast cancer that is called hormone responsive locally advanced or metastatic.

NOLVADEX-D should only be used for the conditions listed above.

How NOLVADEX-D works:

NOLVADEX-D blocks the effects of the hormone estrogen in your body.

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

The ingredients in NOLVADEX-D are:

Medicinal ingredient: tamoxifen citrate

Non-medicinal ingredients: corn starch, croscarmellose sodium, gelatin, lactose, macrogol 300, magnesium stearate, methylhydroxy propylcellulose and titanium dioxide.

NOLVADEX-D comes in the following dosage form:

Tablets; 20 mg

Do not use NOLVADEX-D if:

- you are allergic to tamoxifen citrate, or to any other ingredients in this medicine or part of the container.
- you are pregnant.
- you are under 18 years of age.
- you have had a stroke in the past.
- you have had a pulmonary embolism in the past which is when a blood vessel in your lungs is blocked.
- you have had blood clots in the past, including deep vein thrombosis which is when blood clots form in deep veins like the legs.
- you are taking medicines called anticoagulants used to prevent blood clots, like warfarin.
- you have been told by your healthcare professional that you have an increased risk of developing cancer of the endometrium.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NOLVADEX-D. Talk about any health conditions or problems you may have, including if you:

- are breastfeeding or intend to breastfeed.
- are taking or have recently taken antidepressant medicines such as paroxetine used to improve mood or symptoms of hot flushes.
- have cataracts or other eye problems.
- have decreased white blood cells or platelets in your blood.
- are taking medicines called aromatase inhibitors used for endocrine therapy, such as anastrozole, letrozole or exemestane.
- are taking medicines called cytotoxic agents used to destroy cancer cells.
- have metastatic bone disease or elevated calcium levels (hypercalcemia).
- have a history of hereditary angioedema. This is an inherited condition where fluid builds up outside of the blood vessels. Taking NOLVADEX-D may cause symptoms of hereditary angioedema or make them worse.
- have any heart conditions including heart rhythm problems (arrhythmia, torsade de pointes). The risk of heart rhythm problems (QT interval prolongation) may be increased when using NOLVADEX-D.

Other warnings you should know about:

Pregnancy:

Tell your healthcare professional if you are planning to become pregnant or if you think you might have become pregnant. You must not take NOLVADEX-D if you are pregnant. This is because it may harm your unborn baby. You must use effective birth control while you are

taking NOLVADEX-D and for nine months after you stop taking it. Talk to your healthcare professional about effective methods of birth control.

Breast reconstruction surgery:

Tell your healthcare professional if you are planning to have breast reconstruction surgery called microvascular breast reconstruction. This is where your own tissue is used to make a new breast. It can occur weeks to years after your primary cancer surgery. Taking NOLVADEX-D when you have microvascular breast reconstruction surgery can increase your risk of complications.

Endometrial and uterine cancer and fibroids:

Taking NOLVADEX-D can increase your risk of getting endometrial or uterine cancer or uterine fibroids (non-cancerous tumours in your uterus). Tell your healthcare professional right away if you have any unusual vaginal bleeding or 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 endometrium and uterus may occur, some of which may be serious and could include cancer.

If you go into the hospital, let medical staff know you are taking NOLVADEX-D.

Bone mineral density:

If you are premenopausal, taking NOLVADEX-D may reduce the mineral content of your bones. Talk to your healthcare professional about ways to maintain your bone health while you are taking NOLVADEX-D.

Monitoring and blood tests:

Your healthcare professional may check your heart function and blood electrolyte levels before you start taking NOLVADEX-D and periodically during treatment. They will also monitor your bone health if you are premenopausal.

Driving and using machines:

NOLVADEX-D may make you tired and weak. This may affect your ability to drive and use machines. Before driving or using machines, wait until you are feeling well again.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with NOLVADEX-D:

- Medicines called Selective Serotonin Reuptake Inhibitors (SSRIs) used to treat depression such as paroxetine, a known CYP2D6 inhibitor.
- Medicines used to prevent blood clots such as warfarin.
- Cytotoxic agents.
- Medicines called aromatase inhibitors, which are used to treat breast cancer and include anastrozole, letrozole or exemestane.

How to take NOLVADEX-D:

- Take NOLVADEX-D exactly as your healthcare professional tells you to.
- It is important to keep taking NOLVADEX-D even if you start to feel ill. Do not change your dose or stop taking this medicine without talking to your healthcare professional.
- Stay under your healthcare professional's care while taking NOLVADEX-D.

Usual dose:

The recommended daily dose of NOLVADEX-D is 20 to 40 mg in a single dose or in two divided doses. The lowest effective dose should be used. Your healthcare professional will tell you how much NOLVADEX-D to take and when to take it.

Overdose:

If you think you, or a person you are caring for, have taken too much NOLVADEX-D, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

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 make up for a missed dose.

Possible side effects from using NOLVADEX-D:

These are not all the possible side effects you may have when taking NOLVADEX-D. If you experience any side effects not listed here, tell your healthcare professional.

- Hot flushes
- Itching around the vagina
- Vaginal discharge
- Nausea, vomiting, diarrhea and constipation
- Bad taste in the mouth, loss of taste or distaste to food
- Headaches
- Light-headedness
- Sensory changes (including taste disorder and numbness or tingling in the skin)
- Hair loss
- Leg cramps
- Tingling, numbness or prickling of the skin
- Muscle pain
- Tiredness and weakness
- Disturbances of menstrual function, irregular or missed menstrual periods
- Increased levels of fats in the blood, sometimes with pain or tenderness in the upper abdomen

Serious side effects and what to do about them

Frequency/Side effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very Common			
Depression: Feeling sad, sleeping a lot more or a lot less than usual, changes in weight, withdrawal from social situations, family gatherings		✓	

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	Only if severe	In all cases	
and activities with friends, and reduced sex drive.			
Fluid retention (excess fluid build-up inside the body): Swelling of the hands, feet or ankles.	✓		
Common			
Anemia (decreased red blood cells): Dizziness, feeling tired and weak, loss of energy, shortness of breath.		✓	
Cataracts (change to the cornea or disease of the retina): Disturbances of vision or difficulties in seeing properly.		✓	
Endometrial changes (non-cancerous mass in the inner lining of the vagina): Vaginal bleeding, irregular periods with heavy bleeding.		✓	
Fatty liver (formation of fatty liver cells): Fatigue, malaise, upper abdominal discomfort, general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes).		✓	
Hypersensitivity reactions (allergic reactions): Develop 'nettle rash' or 'hives' (urticaria).			✓
Ischemic cerebrovascular events (stroke): Numbness, paralysis or weakness of the arms or legs, dizziness or confusion, slurred/loss of speech, sudden difficulty walking, difficulty in holding things.			✓
Liver test abnormalities (blood tests showing elevations in liver enzymes): Abdominal pain, nausea, vomiting, abdominal distension, with or without jaundice (yellowing of the skin and eyes).		✓	
Radiation recall (inflammation of skin due to radiation): Redness, peeling, swelling, and/or blistering of the skin in areas previously exposed to radiation therapy.		✓	

Frequency/Side effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Thromboembolic events, including deep vein thrombosis, microvascular thrombosis and pulmonary embolism (clot in blood vessels): Pain, swelling or redness of the calf or leg which may indicate a blood clot in the deep veins of leg. Chest pain or shortness of breath which may indicate a blood clot in lungs.			✓
Tumour flare (inflammation of visible tumour): Increased bone and tumour pain.		✓	
Uterine fibroids (non-cancerous tumours in your uterus): Vaginal bleeding, pelvic discomfort or irregular periods with heavy bleeding.		✓	
Uncommon			
Endometrial cancer (cancers of the inner lining of the endometrium): Vaginal bleeding, pelvic discomfort, irregular periods with heavy bleeding.		✓	
Hypercalcemia (increased calcium levels in the blood): Excessive nausea, vomiting or thirst.		✓	
Interstitial pneumonitis (inflammation of the lungs): Breathlessness and cough.		✓	
Leukopenia (low white blood cell counts): Aches, feeling tired, fever, flu-like symptoms, infections.		✓	
Liver cirrhosis (scarring of the liver): General feeling of being unwell, with or without jaundice (yellowing of the skin and eyes).		✓	
Pancreatitis (inflammation of the pancreas): Prolonged severe abdominal pain with or without vomiting, pain may spread out towards the back, pain or tenderness in upper abdomen.		✓	

Frequency/Side effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Thrombocytopenia (decreased platelets in the blood): Bleeding, bruising, fatigue, weakness.		✓	
Visual disturbances, including retinal crystals, macular edema, keratopathy (abnormal vision, red eye and damage to the retina of the eye): Change in eye colour, difficulty seeing at night or in poor light, eye pain, eye swelling and redness, watery eyes, vision changes, and sensitivity to light.		✓	
Rare			
Agranulocytosis (decreased white blood cells) **and Neutropenia** (decreased counts of neutrophils): Aches, feeling tired, fever, flu-like symptoms, infections.		✓	
Angioedema (swelling due to allergic reaction): Difficulty in breathing with or without swelling of the face, lips, tongue and/or throat and/or swelling of the face, lips, tongue and/or throat which may cause difficulty swallowing.			✓
Bullous pemphigoid (large fluid-filled blisters on skin): Redness, itching of skin and/or blistering of the skin, lips, eyes or mouth.			✓
Cutaneous lupus erythematosus (inflammation of the skin): Rash or redness on areas exposed to light.		✓	
Cutaneous vasculitis (inflammation of the blood vessels): Red spots on skin that don't change colour when pressed, bruise-like marks on the skin, raised skin lumps.		✓	
Endometriosis (abnormal growth of the uterus lining): Painful periods with excessive bleeding, pain on urination or pelvic discomfort/pain.		✓	
Erythema multiforme (allergic skin reaction): Raised red or purple skin patches, possibly with blister or crust in the centre, possibly with mild			✓

Frequency/Side effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
itching or burning; possibly swollen lips.			
Liver abnormalities, including cholestasis, hepatitis, hepatic failure, hepatocellular injury, hepatic necrosis (liver injury): General feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), nausea and vomiting.		✓	
Optic nerve diseases, including optic neuropathy, optic neuritis (damage to optic nerve): Blurred vision, blindness.		✓	
Ovarian cysts (enlargement of the ovaries): Pressure, bloating, swelling or pain in the lower abdomen on the side of the cyst.		✓	
Porphyria cutanea tarda (skin lesions): Skin blisters in areas exposed to the light.		✓	
Severe skin reactions including Stevens-Johnson syndrome and Toxic Epidermal Necrolysis: Fever, redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands.			✓
Uterine cancer (cancers of the uterus): Vaginal bleeding, pelvic discomfort, irregular periods with heavy bleeding.		✓	
Vaginal polyps (non-cancerous mass in the inner lining of the vagina): Vaginal bleeding, irregular periods with heavy bleeding.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store at room temperature (15 to 30°C). Protect from light.

Keep out of reach and sight of children.

If you want more information about NOLVADEX-D:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.astrazeneca.ca, or by calling 1-800-668-6000.

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