


IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION


fulvestrant injection
50 mg/mL

This leaflet is part III of a three-part "Product Monograph" published when FASLODEX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FASLODEX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

FASLODEX is used to treat breast cancer in postmenopausal women.

What it does:

In hormone sensitive breast cancer, estrogen (female sex hormone) promotes tumour growth. By stopping some of the actions of estrogen, FASLODEX reduces the amount that is in the body, which has an effect in reducing breast cancer tumour growth.

When it should not be used:

- If you are allergic to this drug or any of its ingredients (see important nonmedicinal ingredients).
- If you are pregnant or breast-feeding.

What the medicinal ingredient is:

fulvestrant

What the important nonmedicinal ingredients are:

ethanol, benzyl alcohol, benzyl benzoate and castor oil.

What dosage forms it comes in:

Sterile injection solution in pre-filled syringes.
Each pre-filled syringe has 250 mg of fulvestrant.

WARNINGS AND PRECAUTIONS

FASLODEX is not expected to affect your ability to drive or use machines. However, some patients may occasionally feel tired and/or weak. If this happens to you, do not drive or operate machines and ask your doctor for advice. FASLODEX should not be given to children or men.

BEFORE you use FASLODEX talk to your doctor or pharmacist if:

- If you have any problems with your liver or kidneys.

- If you have been told you have a low blood platelet count, problems with bleeding or if you use medicine to prevent blood clots (e.g. anticoagulants).
- If you have a personal or family history of osteoporosis (thinning of the bone), or have low bone density, or have a recent history of fracture.

DURING treatment with FASLODEX, contact your doctor promptly if the following happens to you, as you may need further examination or treatment:

- allergic reactions, including swelling of the face, lips, tongue and/or throat, hives/welts and/or difficulty with swallowing. Such reactions may happen immediately, or several days after injection.

INTERACTIONS WITH THIS MEDICATION

Interactions with other drugs and FASLODEX have not been established. Before using FASLODEX talk to your doctor or pharmacist if you are taking, or have recently taken any other medicines, even those you have bought without prescription.

PROPER USE OF THIS MEDICATION

FASLODEX is to be given as an injection into the muscle (intramuscular) of the buttock. Your healthcare provider will administer this medicine.

Usual dose:

500 mg as two 250 mg/5 mL injections, one in each buttock on days 0, 14 and 28 and then every 28 days thereafter.

Overdose:

In case of suspected drug overdose, contact a health care practitioner, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your scheduled dose, call your doctor immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

During FASLODEX treatment, you may also have the following side effects which are seen when a blood test is taken:

- increased level of liver enzymes (very common)
- increased level of bilirubin (common)
- increased level of an enzyme called Gamma-glutamyl transferase produced in the liver (uncommon)

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very Common			
Injection site reactions, such as pain and/or inflammation		√	
Weakness		√	
Fatigue		√	
Nausea		√	
Joint, muscle and back pain		√	
Hot flushes		√	
Skin rash		√	
Allergic reactions, including swelling of the face, lips, tongue and/or throat, hives/welts and/or difficulty with swallowing. Such reactions may happen immediately, or several days after injection.		√	
Common			
Feelings of numbness, tingling or weakness in your legs following a FASLODEX injection.		√	
Headache		√	
Pain in extremity		√	
Symptoms from the stomach or the bowels, such as vomiting, diarrhea or loss of appetite		√	
Urinary tract infections		√	

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Lower level of platelets (symptoms may include bruising, reddish-purple spots and unusual bleeding)		√	
Uncommon			
Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), liver pain or liver swelling.		√	

If you notice any other side effects, please tell your doctor or pharmacist as soon as possible.

This is not a complete list of side effects. For any unexpected effects while taking FASLODEX, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

FASLODEX must be kept in the refrigerator (2°C-8°C). The pre-filled syringe will normally be stored for you by your doctor or the hospital. The staff is responsible for the correct storage, use and disposal of FASLODEX.

Keep the FASLODEX syringe in its original pack and do not break the seal, in order to protect it from light. The FASLODEX pre-filled syringe should not be used after the expiry date on the pack.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER 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, under Patients with Prescriptions or by contacting the sponsor, AstraZeneca Canada Inc. at:

Questions or Concerns: 1-800-668-6000

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