PART III: CONSUMER INFORMATION

[Pr]Fulvestrant Injection
50 mg / mL

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

ABOUT THIS MEDICATION

What the medication is used for:
Fulvestrant Injection 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, Fulvestrant Injection 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:
Benzyl alcohol, benzyl benzoate, castor oil and dehydrated alcohol.

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

Fulvestrant Injection 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. Fulvestrant Injection should not be given to children or men.

BEFORE you use Fulvestrant Injection 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.
- If you can become pregnant, you should use effective contraception while you are being treated with Fulvestrant Injection and for 2 years after your last dose.

DURING treatment with Fulvestrant Injection, 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 fulvestrant injection have not been established. Before using Fulvestrant Injection 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

Fulvestrant Injection 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:

If you think you have taken too much Fulvestrant Injection, contact your healthcare professional, 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, Fulvestrant Injection can have side effects. Tell your doctor as soon as possible if any of the following side effects bothers you or continues.

During Fulvestrant Injection 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 seek immediate emergency medical attention
	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 Fulvestrant Injection.		✓	
Headache		✓	
Pain in extremity		✓	
Symptoms from the stomach or the bowels, such as vomiting, diarrhea or loss of appetite		✓	
Urinary tract infections		✓	
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 Fulvestrant Injection, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

Fulvestrant Injection 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 Fulvestrant Injection.

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

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

MORE INFORMATION

If you want more information about Fulvestrant Injection:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; or by calling 1-844-596-9526

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Last Revised: December 30, 2019.

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