

# FASLODEX™

*fulvestrant*

---

## Consumer Medicine Information

Name of consumer

Address of consumer

---

---

### What is in this leaflet

---

This leaflet answers some of the common questions people ask about **FASLODEX**. It does not contain all the information that is known about **FASLODEX**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **FASLODEX** against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

---

### What FASLODEX is for

---

**FASLODEX** is used to treat hormone receptor positive, locally advanced or metastatic breast cancer in women who have been through menopause and have received prior treatment with tamoxifen.

**FASLODEX** stops some of the actions of oestrogen within the body. Oestrogen is a female sex hormone that may help cancer cells grow in women with breast cancer.

**FASLODEX** should only be given to women.

**FASLODEX** is not recommended for use in men or children.

**FASLODEX** does not kill cancer cells, however it stops or slows their growth.

Your doctor will have explained why you are being treated with **FASLODEX** and will determine what dose to give you.

**Follow all directions given to you by your doctor.**

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

**FASLODEX** is not addictive

---

### Before you are given FASLODEX

---

#### **When you must not use it**

**Do not use FASLODEX if you have any allergies to the active ingredient fulvestrant, or any ingredients used in FASLODEX**

**Do not use FASLODEX if you have not reached menopause.** We do not have information on its use in women before menopause.

**Do not use FASLODEX if you are pregnant or breastfeeding.** We do not know if it is safe for you to be given it while you are pregnant. It may affect your baby if you are given it at any time during pregnancy.

Do not use **FASLODEX** if you are breastfeeding.

**FASLODEX should not be given to children.**

There is no information on its use in children.

**FASLODEX should not be given to men.**

There is no information on its use in men.

**FASLODEX injection should only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.**

#### **Before you are given it**

**You must tell your doctor if:**

1. **you have any allergies to**
  - any medicines
  - any other substances, such as foods, preservatives or dyes

If you have an allergic reaction, you may get a skin rash, hayfever, difficulty breathing or feel faint.

2. **you have any of these medical conditions**
  - liver problems
  - kidney problems
  - bleeding disorders

- a low blood platelet count

It may not be safe for you to be given **FASLODEX** if you have any of these conditions.

### **Taking other medicines**

**Tell your doctor if you are taking any other medicines, including:**

- tamoxifen or any medicine which contains oestrogen (female sex hormone). These medicines may reduce the effect of **FASLODEX**
- other medicines used to treat cancer
- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way **FASLODEX** works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you are given **FASLODEX**.

### **How FASLODEX is given**

**FASLODEX** will be given to you by injection by your doctor or nurse.

The injection will be given into the muscle in your buttock.

**FASLODEX** injection is usually given once a month but your doctor will decide the exact dose. The dose is usually given as a single injection.

### **Overdose**

**The doctor or nurse giving you FASLODEX will be experienced in its use, so it is extremely unlikely that you will be given too much.**

## **While you are using it**

### **Things you must do**

**Be sure to keep all your appointments with your doctor so your progress can be checked.**

**Tell any other doctors, dentists and pharmacists who are treating you that you have been given FASLODEX.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you have been given FASLODEX.**

If you go into hospital, please let the medical staff know that you are being treated with **FASLODEX**.

### **Things to be careful of**

**Be careful driving or operating machinery until you know how FASLODEX affects you.**

Some patients may occasionally feel weak, tired or sleepy.

### **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FASLODEX.**

**FASLODEX** helps most people with breast cancer, but it may have unwanted side-effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- pain or inflammation at the injection site
- hot flushes
- headache
- weakness, tiredness, sleepiness
- nausea or vomiting
- diarrhoea
- loss of appetite
- skin rash
- urinary tract infections
- hypersensitivity, including swelling of the face, lips, tongue and/or throat and hives/welts

These are all possible side effects of **FASLODEX**.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may get other side effects while being treated with **FASLODEX**.

## **After using it**

### **Storage**

**FASLODEX should be stored in a fridge (2°C – 8°C) until ready for use. Your doctor or pharmacist will usually store the medicine for you.**

### **Disposal**

**Your doctor or pharmacist will dispose of any needles, syringes and FASLODEX that may be left over.**

## **Product description**

### **What FASLODEX looks like**

**FASLODEX** is a clear, colourless to yellow viscous liquid for injection. It is available in 5mL pre-filled syringes.

### **Ingredients**

FASLODEX contains 250mg/5mL  
of the active ingredient fulvestrant

plus  
ethanol  
benzyl alcohol  
benzyl benzoate  
castor oil

---

## **Distributor**

---

AstraZeneca Pty Ltd  
ABN 54 009 682 311  
Alma Road  
NORTH RYDE NSW 2113

Tel: 1 800 805 342

This leaflet was prepared on 7 May  
2007

Australian Registration Number  
5mL pre filled syringe  
AUST R 106955