

FASLODEX[®]

fulvestrant

Consumer Medicine Information

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 women who have been through menopause with:

- hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, locally advanced or metastatic breast cancer who have not been previously treated with endocrine therapy.
- HR positive, locally advanced or metastatic breast cancer who have progressive disease following prior endocrine (anti-oestrogen or aromatase inhibitor) therapy.

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 of the other 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.

It is not known 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. If you can become pregnant, you should use effective contraception while you are being treated with FASLODEX and for 2 years after the last dose.

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, swelling of the extremities, 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

The usual dose is 500 mg fulvestrant (two (2) x 250 mg/5 ml injections) given once a month with an additional 500 mg dose given 2 weeks after the initial dose.

Your doctor or nurse will give you FASLODEX as a slow intramuscular injection, one into each of your buttocks

Overdose

The doctor or nurse giving you FASLODEX will be experienced in its use, so it is unlikely that you will be given too much. If you are concerned that you have been given too much Faslodex, tell your doctor or nurse

immediately. Otherwise telephone the Poisons Information Centre (telephone 13 11 26) for advice.

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

- joint or muscle pain.

These are all possible side effects of FASLODEX.

FASLODEX may be associated with changes in your blood, urine or liver. Your doctor may want to perform tests from time to time to check on your progress and detect any unwanted side effects.

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. Each pack contains two (2) x 5mL pre-filled syringes.

Ingredients

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

plus

ethanol

benzyl alcohol

benzyl benzoate

castor oil

Supplier

FASLODEX is sponsored and supplied in Australia by:

AstraZeneca Pty Ltd

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