

Fulvestrant Sandoz®

Fulvestrant, 250 mg/ 5 mL, solution for injection

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

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 **Fulvestrant Sandoz** 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 Fulvestrant Sandoz is used for

Fulvestrant Sandoz is used to treat oestrogen receptor positive breast cancer that is locally advanced or has spread to other parts of the body (metastatic) in women who have been through menopause.

Fulvestrant Sandoz 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.

Fulvestrant Sandoz should only be given to women. **Fulvestrant Sandoz** is not recommended for use in men or children.

Fulvestrant Sandoz does not kill cancer cells, however it stops or slows their growth.

Your doctor will have explained why you are being treated with **Fulvestrant Sandoz** 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.

This medicine is only available with a doctor's prescription.

Fulvestrant Sandoz is not addictive.

Before you are given Fulvestrant Sandoz

When you must not be given this medicine

You should not be given this medicine if you have an allergy to:

- fulvestrant or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You should not be given this medicine if you are pregnant. It may affect your developing baby if you use it during pregnancy. If you can become pregnant, you should use effective contraception while you are being treated with **Fulvestrant Sandoz** and for 2 years after your last dose.

You should not be given this medicine if you are breast-feeding.

Fulvestrant Sandoz should not be given to children. There is no information on its use in children.

Fulvestrant Sandoz should not be given to men. There is no information on its use in men.

Fulvestrant Sandoz 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 this medicine

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 **Fulvestrant Sandoz** 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 **Fulvestrant Sandoz**
- other medicines used to treat cancer
- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way **Fulvestrant Sandoz** 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 **Fulvestrant Sandoz**.

How Fulvestrant Sandoz is given to you

Your doctor or nurse will give you **Fulvestrant Sandoz** as a slow intramuscular injection, one into each of your buttocks.

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

Fulvestrant Sandoz will be slowly injected into the muscle of each of your buttocks.

While you are being treated with Fulvestrant Sandoz

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 **Fulvestrant Sandoz**.

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

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

Things to be careful of

Be careful driving or operating machinery until you know how Fulvestrant Sandoz affects you. Some patients may occasionally feel weak, tired or sleepy.

Overdose

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

Telephone your doctor or the National Poisons Information Centre on 0800 POISON (0800 764 766) or go to casualty at your nearest hospital immediately if you think that you or anyone else may have administered too much **Fulvestrant Sandoz**. Even if there are no signs of discomfort or poisoning.

Side effects

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

Fulvestrant Sandoz 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 **Fulvestrant Sandoz**.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Fulvestrant Sandoz**.

After using Fulvestrant Sandoz

Storage

Fulvestrant Sandoz should be stored below 25°C. Your doctor or pharmacist will usually store the medicine for you.

Disposal

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

Product description

What it looks like

Fulvestrant Sandoz is a clear, colourless to yellow viscous liquid for injection. Each pack contains two (2) x 5 mL pre-filled syringes.

Ingredients

Each **Fulvestrant Sandoz** syringe contains 250 mg/5 mL of the active ingredient fulvestrant.

Other ingredients include:

- ethanol
- benzyl alcohol
- benzyl benzoate
- castor oil

Marketed by:

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