

Fulvestrant Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Fulvestrant Sandoz?

Fulvestrant Sandoz contains the active ingredient fulvestrant. Fulvestrant Sandoz is used to treat women who have been through menopause with hormone receptor positive, human epidermal growth factor receptor 2 negative, locally advanced or metastatic breast cancer who have not been previously treated with endocrine therapy. It is also used to treat hormone receptor positive, locally advanced or metastatic breast cancer who have progressive disease following prior endocrine therapy.

For more information, see Section [1. Why am I being given Fulvestrant Sandoz?](#) in the full CMI.

2. What should I know before I am given Fulvestrant Sandoz?

Do not use if you have ever had an allergic reaction to fulvestrant or any of the ingredients listed at the end of the CMI. Do not use Fulvestrant Sandoz if you are pregnant. Do not use Fulvestrant Sandoz if you have not reached menopause. Fulvestrant Sandoz should not be given to men or children.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Fulvestrant Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fulvestrant Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Fulvestrant Sandoz?

- Fulvestrant Sandoz will be given to you by a doctor or nurse as a slow intramuscular injection.

More instructions can be found in Section [4. How will I be given Fulvestrant Sandoz?](#) in the full CMI.

5. What should I know while being given Fulvestrant Sandoz?

Things you should do	<ul style="list-style-type: none">Be sure to keep all your doctor's appointment.Tell your doctor if you are taking tamoxifen or any medicine which contains estrogen (female sex hormone).
Things you should not do	<ul style="list-style-type: none">Do not use Fulvestrant Sandoz if you have not reached menopause.Do not use Fulvestrant Sandoz if you are pregnant or breastfeeding.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Fulvestrant Sandoz affects you.Fulvestrant Sandoz may make some people feel weak, tired or sleepy.

For more information, see Section [5. What should I know while being given Fulvestrant Sandoz?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Some common side effects are: 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Fulvestrant Sandoz[®]

Active ingredient(s): *fulvestrant*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fulvestrant Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fulvestrant Sandoz.**

Where to find information in this leaflet:

- [1. Why am I being given Fulvestrant Sandoz?](#)
- [2. What should I know before I am given Fulvestrant Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Fulvestrant Sandoz?](#)
- [5. What should I know while being given Fulvestrant Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Fulvestrant Sandoz?

Fulvestrant Sandoz contains the active ingredient fulvestrant. Fulvestrant Sandoz stops some of the actions of estrogen within the body. Estrogen is a female sex hormone that may help cancer cells grow in women with breast cancer.

Fulvestrant Sandoz 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.**

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.

2. What should I know before I am given Fulvestrant Sandoz?

Warnings

Do not use Fulvestrant Sandoz if:

- you are allergic to fulvestrant, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Fulvestrant Sandoz should not be given to women before menopause, men or children.

There is no information on its use in women before menopause, men or children.

Fulvestrant Sandoz 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.

Check with your doctor if you:

- have any other medical conditions:
 - liver problems
 - kidney problems
 - bleeding disorders
 - a low blood platelet count
- take any medicines for any other condition

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use Fulvestrant Sandoz 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 Fulvestrant Sandoz, and for 2 years after the last dose.

Do not use Fulvestrant Sandoz if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Fulvestrant Sandoz may interfere with each other.

Tell your doctor if you are taking:

- tamoxifen or any medicine which contains estrogen (female sex hormone). These medicines may reduce the effect of Fulvestrant Sandoz.
- other medicine used to treat cancer.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fulvestrant Sandoz.

4. How will I be given Fulvestrant Sandoz?

Fulvestrant Sandoz will be given to you by a doctor or a nurse as a slow intramuscular injection, one into each of your buttocks.

How much will be 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.

If you receive too much Fulvestrant Sandoz

Since Fulvestrant Sandoz is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. If you think that you have used too much Fulvestrant Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Fulvestrant Sandoz?

Things you should do

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Fulvestrant Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given Fulvestrant Sandoz.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fulvestrant Sandoz affects you.

Fulvestrant Sandoz generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Fulvestrant

Sandoz may cause weakness, sleepiness or tiredness in some people.

Looking after your medicine

Fulvestrant Sandoz should be stored below 25°C.

The hospital will store Fulvestrant Sandoz under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Fulvestrant Sandoz that may be left over.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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• back pain	Speak to your doctor if you have any of these less serious side effects and they worry you.

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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at

<https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

Fulvestrant Sandoz is not addictive.

What Fulvestrant Sandoz contains

Active ingredient (main ingredient)	fulvestrant
Other ingredients (inactive ingredients)	ethanol benzyl alcohol benzyl benzoate castor oil

Do not take this medicine if you are allergic to any of these ingredients.

What Fulvestrant Sandoz looks like

Fulvestrant Sandoz – clear, colourless to yellow viscous liquid for injection. Each pack contains two (2) x 5 mL pre-filled syringes. (Aust R 323030).

Who distributes Fulvestrant Sandoz

Fulvestrant Sandoz is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Fulvestrant Sandoz is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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