

FULVESTRANT ACCORD

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 Accord?

Fulvestrant Accord 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 using Fulvestrant Accord?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to any medicine containing fulvestrant or any of the ingredients listed at the end of the CMI. Do not use Fulvestrant Accord if you are pregnant. Do not use Fulvestrant Accord if you have not reached menopause. Fulvestrant Accord 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 Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fulvestrant Accord 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 Accord?

Fulvestrant Accord 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 Accord?](#) in the full CMI.

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

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 oestrogen (female sex hormone).
Things you should not do	<ul style="list-style-type: none">• Do not use Fulvestrant Accord if you have not reached menopause.• Do not use Fulvestrant Accord if you are pregnant or breastfeeding.
Driving or using machines	Be careful driving or operating machinery until you know how Fulvestrant Accord affects you. Fulvestrant Accord may make some people feel weak, tired or sleep.

For more information, see Section [5. What should I know while being given Fulvestrant Accord?](#) 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 ACCORD

Active ingredient(s): *fulvestrant*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fulvestrant Accord. **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 Accord.**

Where to find information in this leaflet:

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

1. Why am I being given Fulvestrant Accord?

Fulvestrant Accord contains the active ingredient fulvestrant. Fulvestrant Accord 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 or HR positive, locally advanced or metastatic breast cancer who have progressive disease following prior endocrine (anti-oestrogen or aromatase inhibitor) therapy.

Fulvestrant Accord 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 Accord should only be given to women.

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

Your doctor may prescribe Fulvestrant Accord for another purpose.

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

Warnings

You must not be given Fulvestrant Accord if:

- you are allergic to active ingredient fulvestrant or to any of the other ingredients listed at the end of this leaflet.

Fulvestrant Accord 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.

Tell your doctor if you have any of the following medical

conditions:

- liver problems
- kidney problems
- bleeding disorders
- a low blood platelet count

It may not be safe for you to be given Fulvestrant Accord 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 Accord 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 Accord and for 2 years after the last dose.

Do not use Fulvestrant Accord 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 Accord may interfere with each other.

Tell your doctor if you are taking:

- tamoxifen or any medicine which contains oestrogen (female sex hormone). These medicines may reduce the effect of Fulvestrant Accord
- 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 Accord.

4. How will I be given Fulvestrant Accord?

Fulvestrant Accord 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 Accord

Since Fulvestrant Accord 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 been given too much Fulvestrant Accord.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, nurse, or pharmacist.

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

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 Accord.

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

Driving or using machines

Be careful driving or operating machinery until you know how Fulvestrant Accord affects you.

Fulvestrant Accord generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Fulvestrant Accord may cause weakness, sleepiness or tiredness in some people.

Looking after your medicine

The hospital will store Fulvestrant Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Fulvestrant Accord 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.

Common side effects

Common 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	Speak to your doctor if you have any of these common side effects and they worry you.

Common side effects	What to do
<ul style="list-style-type: none">• urinary tract infections• hypersensitivity, including swelling of the face, lips, tongue and/or throat and hives/welts• joint or muscle pain	

Fulvestrant Accord 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. 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 Accord is not addictive.

What Fulvestrant Accord 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 Accord looks like

Fulvestrant Accord is a clear, colourless to yellow viscous liquid for injection supplied in a pre-filled syringe. It is supplied as a single or pack of two. (250 mg/5 mL: AUST R 328533).

Who distributes Fulvestrant Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

This leaflet was prepared in June 2022.