

FULVESTRANT EVER PHARMA

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 using FULVESTRANT EVER PHARMA?

FULVESTRANT EVER PHARMA contains the active ingredient fulvestrant. FULVESTRANT EVER PHARMA 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.

For more information, see Section [1. Why am I using FULVESTRANT EVER PHARMA?](#) in the full CMI.

2. What should I know before I use FULVESTRANT EVER PHARMA?

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.

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 use FULVESTRANT EVER PHARMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FULVESTRANT EVER PHARMA 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 do I use FULVESTRANT EVER PHARMA?

- 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 FULVESTRANT EVER PHARMA as a slow intramuscular injection, one into each of your buttocks

More instructions can be found in Section [4. How do I use FULVESTRANT EVER PHARMA?](#) in the full CMI.

5. What should I know while using FULVESTRANT EVER PHARMA?

Things you should do	<ul style="list-style-type: none">• 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 EVER PHARMA• If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you have been given FULVESTRANT EVER PHARMA.
Driving or using machines	Be careful driving or operating machinery until you know how FULVESTRANT EVER PHARMA affects you.
Drinking alcohol	FULVESTRANT EVER PHARMA contains 500 mg of alcohol (ethanol) per syringe which is equivalent to alcohol 10 % v/v. The small amount of alcohol in this medicine will not have any noticeable effects. To be taken into account in pregnant or breast-feeding women and high-risk groups such as patients with liver disease, or epilepsy.
Looking after your medicine	FULVESTRANT EVER PHARMA does not require any special storage conditions. Store below 25°C. Store in original pack

For more information, see Section [5. What should I know while using FULVESTRANT INTERPHARMA?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you experience hot flushes, weakness, tiredness, sleepiness, joint or muscle pain, skin rash, hypersensitivity, including swelling of the face, lips, tongue and/or throat and hives/welts, pain or inflammation at the injection site, headache, nausea or vomiting, diarrhea, loss of appetite, and urinary tract infections. These are some common side effects that may be experienced. 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. 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 EVER PHARMA

Active ingredient(s): *fulvestrant*

Consumer Medicine Information (CMI)

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

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 EVER PHARMA 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.

Where to find information in this leaflet:

- [1. Why am I using FULVESTRANT EVER PHARMA?](#)
- [2. What should I know before I use FULVESTRANT EVER PHARMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FULVESTRANT EVER PHARMA?](#)
- [5. What should I know while using FULVESTRANT EVER PHARMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FULVESTRANT EVER PHARMA®?

FULVESTRANT EVER PHARMA contains the active ingredient **fulvestrant**. FULVESTRANT EVER PHARMA® is an anti-estrogen belonging to the group of medicines for endocrine therapy.

FULVESTRANT EVER PHARMA 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 EVER PHARMA should only be given to women.

FULVESTRANT EVER PHARMA is not recommended for use in men or children.

FULVESTRANT EVER PHARMA does not kill cancer cells, however it stops or slows their growth.

Your doctor will have explained why you are being treated with FULVESTRANT EVER PHARMA 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.

FULVESTRANT EVER PHARMA is not addictive.

FULVESTRANT EVER PHARMA 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.

2. What should I know before I use FULVESTRANT EVER PHARMA?

Warnings

Do not use FULVESTRANT EVER PHARMA if:

- you have any allergies to the active ingredient fulvestrant, or any of the other ingredients used in FULVESTRANT EVER PHARMA.**
- you have not reached menopause.** We do not have information on its use in women before menopause.
- you are pregnant or breastfeeding.**

Check with your doctor if 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 EVER PHARMA 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

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 EVER PHARMA and for 2 years after the last dose.

Do not use FULVESTRANT EVER PHARMA if you are breastfeeding.

FULVESTRANT EVER PHARMA should not be given to:

- Children.** There is no information on its use in children.
- Men.** There is no information on its use in men.

FULVESTRANT EVER PHARMA 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 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.

3. What if I am 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 EVER PHARMA
- 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 EVER PHARMA 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 EVER PHARMA.

4. How do I use FULVESTRANT EVER PHARMA?

How much to take / use

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 FULVESTRANT EVER PHARMA as a slow intramuscular injection, one into each of your buttocks

If you use too much FULVESTRANT EVER PHARMA

The doctor or nurse giving you FULVESTRANT EVER PHARMA 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 FULVESTRANT EVER PHARMA, tell your doctor or nurse immediately.

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

5. What should I know while using FULVESTRANT EVER PHARMA?

Things you should 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 EVER PHARMA.

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

If you go into hospital, please let the medical staff know that you are being treated with FULVESTRANT EVER PHARMA.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using FULVESTRANT EVER PHARMA.

Driving or using machines

Be careful driving or operating machinery until you know how FULVESTRANT EVER PHARMA affects you.

Some patients may occasionally feel weak, tired or sleepy.

Looking after your medicine

Storage

FULVESTRANT EVER PHARMA does not require any special storage conditions. Store below 25°C. Store in original pack.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any needles, syringes and FULVESTRANT EVER PHARMA that may be left over.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FULVESTRANT EVER PHARMA.

FULVESTRANT EVER PHARMA 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.

Less serious side effects

Less serious side effects	What to do
Whole body-related: <ul style="list-style-type: none">• hot flushes	Tell your doctor if you notice

Less serious side effects	What to do
<ul style="list-style-type: none"> weakness, tiredness, sleepiness joint or muscle pain. skin rash hypersensitivity, including swelling of the face, lips, tongue and/or throat and hives/welts <p>Injection site related:</p> <ul style="list-style-type: none"> pain or inflammation at the injection site <p>Nervous system(head)-related:</p> <ul style="list-style-type: none"> headache <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> nausea or vomiting diarrhoea loss of appetite <p>Urinary system-related:</p> <ul style="list-style-type: none"> urinary tract infections 	<p>any of the following and they worry you</p>

FULVESTRANT EVER PHARMA 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.

Some people may get other side effects while being treated with FULVESTRANT EVER PHARMA.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the authorities as follows:

In Australia: Report to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

In New Zealand: Report to Medsafe at: <https://pophealth.my.site.com/carmreportnz/>

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.

What FULVESTRANT EVER PHARMA contains

Active ingredient (main ingredient)	Each FULVESTRANT EVER PHARMA syringe contains 250mg/5mL of the active ingredient fulvestrant
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Other ingredients (inactive ingredients)	ethanol benzyl alcohol benzyl benzoate castor oil
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Do not take this medicine if you are allergic to any of these ingredients.

What FULVESTRANT EVER PHARMA looks like

FULVESTRANT EVER PHARMA is a clear, colourless to yellow viscous liquid for injection. FULVESTRANT EVER PHARMA is supplied in packs of one (1) or two (2) x 5mL pre-filled syringes. (AUST R 349711).

Who distributes FULVESTRANT EVER PHARMA

Australia

FULVESTRANT EVER PHARMA is sponsored and supplied in Australia by:

InterPharma Pty Ltd
Suite 103, 39 East Esplanade
MANLY NSW 2095

New Zealand

Healthcare Logistics sponsor and supplied in NZ on behalf of InterPharma Pty Ltd

58 Richard Pearse Drive
Airport Oaks
Mangere 2022
Phone 09 9185100

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