

## PATIENT INFORMATION

### Fulvestrant injection

#### **What is Fulvestrant injection?**

Fulvestrant injection is a prescription medicine used to treat advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic).

Fulvestrant injection may be used alone, if you have gone through menopause, and your advanced breast cancer is:

- hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and has not been previously treated with endocrine therapy

**or**

- HR-positive and has progressed after endocrine therapy.

Fulvestrant injection may be used in combination with ribociclib, if you have gone through menopause, and your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has not been previously treated with endocrine therapy or has progressed after endocrine therapy.

Fulvestrant injection may be used in combination with palbociclib or abemaciclib if your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has progressed after endocrine therapy.

When Fulvestrant injection is used in combination with palbociclib, abemaciclib, or ribociclib, also read the Patient Information for the prescribed product.

It is not known if Fulvestrant injection is safe and effective in children.

It is not known if Fulvestrant injection is safe and effective in people with severe liver problems.

#### **Who should not receive Fulvestrant injection?**

**Do not receive Fulvestrant injection if you** have had an allergic reaction to fulvestrant or any of the ingredients in Fulvestrant injection. See the end of this leaflet for a list of the ingredients in Fulvestrant injection.

Symptoms of an allergic reaction to Fulvestrant injection may include:

- itching or hives
- swelling of your face, lips, tongue or throat
- trouble breathing

**What should I tell my healthcare provider before receiving Fulvestrant injection?**

**Before receiving Fulvestrant injection, tell your healthcare provider about all of your medical conditions, including if you:**

- have a low level of platelets in your blood or bleed easily.
- have liver problems.
- are pregnant or plan to become pregnant. Fulvestrant injection can harm your unborn baby.

**Females who are able to become pregnant:**

- Your healthcare provider may perform a pregnancy test within 7 days before you start Fulvestrant injection.
  - You should use effective birth control during treatment with Fulvestrant injection and for one year after the last dose of Fulvestrant injection.
  - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with Fulvestrant injection.
- are breastfeeding or plan to breastfeed. It is not known if Fulvestrant injection passes into your breast milk. Do not breastfeed during your treatment with Fulvestrant injection and for one year after the final dose of Fulvestrant injection. Talk to your healthcare provider about the best way to feed your baby during this time.

**Tell your healthcare provider about all the medicines you take, including** prescription and over-the-counter medicines, vitamins, and herbal supplements. Fulvestrant injection may affect the way other medicines work, and other medicines may affect how Fulvestrant injection works.

**Especially tell your healthcare provider** if you take a blood thinner medicine.

**How will I receive Fulvestrant injection?**

- Your healthcare provider will give you Fulvestrant injection by injection into the muscle of each buttock.
- Your healthcare provider may change your dose of Fulvestrant injection if needed.

**What are the possible side effects of Fulvestrant injection?**

**Fulvestrant injection may cause serious side effects, including:**

- **Injection site related nerve damage.** Call your healthcare provider if you develop any of the following symptoms in your legs following a Fulvestrant injection:
  - numbness
  - tingling
  - weakness

The most common side effects of Fulvestrant injection include:

- injection site pain
- nausea
- muscle, joint, and bone pain
- headache
- back pain
- tiredness
- pain in arms, hands, legs, or feet
- hot flashes
- vomiting
- loss of appetite
- weakness
- cough
- shortness of breath
- constipation
- increased liver enzymes
- diarrhea

Fulvestrant injection may cause fertility problems in males and females. Talk to your healthcare provider if you plan to become pregnant.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects with Fulvestrant injection. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of Fulvestrant injection**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Fulvestrant injection that is written for health professionals.