PATIENT INFORMATION
WILSERDLY™ (wil-SERD-lee)
(giredestrant)
capsules, for oral use

What is WILSERDLY?

WILSERDLY is a prescription medicine used:

- alone to treat adults with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-), breast cancer that is in early stages (stage I, II, or III) at intermediate to high risk of cancer coming back.
- in combination with the medicine everolimus to treat adults with ER+, HER2- breast cancer that has an estrogen receptor-1 (*ESR1)* gene mutation and has spread to nearby tissue or lymph nodes (locally advanced) or to other parts of the body (metastatic) whose cancer:
  - has come back during or after finishing hormone (endocrine) treatment given after surgery (adjuvant therapy), **or**
  - has worsened after at least one type of endocrine treatment for metastatic cancer.

When WILSERDLY is used in combination with everolimus, your healthcare provider will perform a test to make sure that WILSERDLY is right for you.

It is not known if WILSERDLY is safe and effective in children.

Before taking WILSERDLY, tell your healthcare provider about all of your medical conditions, including if you:

- have a slow heart rate (bradycardia)
- are pregnant or plan to become pregnant. WILSERDLY can harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with WILSERDLY.
  - Use effective non-hormonal birth control (contraception) during treatment with WILSERDLY and for 2 weeks after the last dose of WILSERDLY. Talk to your healthcare provider about birth control methods that may be right for you.
  - If you are taking WILSERDLY in combination with everolimus, your healthcare provider will tell you how long you should use birth control (contraception).
  - Tell your healthcare provider right away if you become pregnant during treatment with WILSERDLY or think you may be pregnant.

  Males with female partners who are able to become pregnant:
  - Use effective birth control (contraception) during treatment with WILSERDLY, and for 2 weeks after the last dose of WILSERDLY.
- are breastfeeding or plan to breastfeed. It is not known if WILSERDLY passes into your breast milk. **Do not** breastfeed during treatment with WILSERDLY and for 2 weeks after the last dose of WILSERDLY. Talk to your healthcare provider about the best way to feed your baby during this time.
- have an intolerance to some sugars found in milk and milk products. WILSERDLY capsules contain lactose monohydrate.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Taking WILSERDLY with certain other medicines may affect how WILSERDLY works and may cause side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take WILSERDLY?

- Take WILSERDLY exactly as your healthcare provider tells you to take it.
- **Do not** change your dose or stop taking WILSERDLY unless your healthcare provider tells you to.
- Your healthcare provider may temporarily or permanently stop treatment with WILSERDLY if you have side effects.
- Take WILSERDLY 1 time a day, at about the same time each day.
- Take WILSERDLY with or without food.
- Swallow WILSERDLY capsule whole. **Do not** open, chew, or crush the capsules before swallowing.
- If you miss a dose of WILSERDLY, take the missed dose as soon as possible on the same day and take the next dose at your regularly scheduled time.

- If you vomit after taking a dose of WILSERDLY, do not take an extra dose. Take your next dose at your regularly scheduled time the next day.
- For women who have not yet reached menopause or are just starting menopause, your healthcare provider may prescribe a medicine called a gonadotropin-releasing hormone (GnRH) agonist.
- For men, your healthcare provider may prescribe a gonadotropin-releasing hormone (GnRH) agonist.

What should I avoid while taking WILSERDLY?

Avoid eating grapefruit and drinking grapefruit juice during treatment with WILSERDLY. Grapefruit may increase the amount of WILSERDLY in your blood.

What are the possible side effects of WILSERDLY?

WILSERDLY can cause serious side effects, including:

- **Slow heart rate (bradycardia).** WILSERDLY can cause your heart rate to slow down. Your healthcare provider will monitor your heart rate more frequently if you have a history of a slow heart rate or take certain heart medicines. Tell your healthcare provider if you develop any signs and symptoms of a slow heart rate, including:
  - dizziness
  - lightheadedness
  - fainting
  - shortness of breath
  - chest pain
  - tiredness

The most common side effects and abnormal blood test results of WILSERDLY alone include:

- muscle and joint pain
- decreased white blood cell counts
- increased liver enzymes (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and alkaline phosphatase [ALP])
- sudden feelings of heat and sweating (hot flash)
- increased triglycerides and cholesterol blood levels
- tiredness
- decreased red blood cell counts
- increased calcium blood levels
- headache
- decreased calcium blood levels
- increased potassium blood levels
- increased creatinine blood levels (kidney function test)
- nausea
- decreased sodium blood levels
- slow heart rate
- decreased potassium blood levels
- COVID-19

The most common side effects and abnormal blood test results of WILSERDLY in combination with everolimus include:

- decreased red blood cell counts
- decreased white blood cell counts
- increased liver enzymes (AST and ALT)
- mouth sores (stomatitis)
- decreased platelet counts
- decreased calcium blood levels
- decreased potassium blood levels
- rash
- increased creatinine blood levels (kidney function test)
- tiredness
- decreased sodium blood levels
- diarrhea
- muscle and joint pain
- lung or breathing problems
- nausea

WILSERDLY may affect fertility in males and in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of WILSERDLY.

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

How should I store WILSERDLY?

- Store WILSERDLY at room temperature between 68ºF and 77ºF (20ºC and 25ºC).
- Store WILSERDLY in the original bottle.
- Keep the bottle tightly closed to protect from light and moisture.

Keep WILSERDLY and all medicines out of the reach of children.

General information about the safe and effective use of WILSERDLY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use WILSERDLY for a condition for which it was not prescribed. Do not give WILSERDLY to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about WILSERDLY that is written for health professionals.

What are the ingredients in WILSERDLY?

Active ingredient: giredestrant

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. The capsule shell contains black iron oxide, hypromellose, red iron oxide, titanium dioxide, and yellow iron oxide. The printing ink contains propylene glycol, shellac, and titanium dioxide.

Distributed by: Genentech USA, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990

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For more information, go to www.WILSERDLY.com or call 1-877-436-3683.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 11/2026