

TREZILENT[®] Film-coated Tablets

Alpelisib (50mg, 150mg, 200mg)

What is in this leaflet

1. What Trezilent[®] is used for
2. How Trezilent[®] works
3. Before you use Trezilent[®]
4. How to use Trezilent[®]
5. While you are using it
6. Side effects
7. Storage and Disposal of Trezilent[®]
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Trezilent[®] is used for

Trezilent[®] is a prescription medicine used in combination with the medicine fulvestrant to treat women who have gone through menopause and men:

- who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene, **and**
- whose disease has progressed on or after endocrine therapy.

Your healthcare provider will test your cancer for an abnormal “PIK3CA” gene to make sure that Trezilent[®] is right for you.

It is not known if Trezilent[®] is safe and effective in children.

How Trezilent[®] works

Trezilent[®] works by blocking the effects of enzymes called phosphatidylinositol-3-kinases (PI3K) which signal cancer cells to grow and multiply. By blocking these enzymes, Trezilent[®] can reduce cancer cell growth and the ability to make new cancer cells, and can destroy cancer cells. Trezilent[®] has to be used together with another medicine called fulvestrant.

If you have any questions about how Trezilent[®] works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

Before you use Trezilent[®]

- When you must not use it

Do not take Trezilent[®] if you have had a severe allergic reaction to Trezilent[®] or

are allergic to any of the ingredients in Trezilent[®].

See the end of this Patient Information leaflet for a complete list of the ingredients in Trezilent[®]. See “Things to be careful of” for signs and symptoms of severe allergic reactions.

Pregnancy and lactation

Trezilent[®] may harm your unborn baby. Females who are able to become pregnant:

- Your healthcare provider will check to see if you are pregnant before you start treatment with Trezilent[®].
- You should use effective birth control (contraception) during treatment with Trezilent[®] and for 1 week after the last dose.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- If you become pregnant or think you are pregnant, tell your healthcare provider right away.

Males with female partners who are able to become pregnant:

- You should use condoms and effective birth control during treatment with Trezilent[®] and for 1 week after the last dose.
- If your female partner becomes pregnant, tell your healthcare provider right away.

It is not known if Trezilent[®] passes into your breast milk. Do not breastfeed during treatment with Trezilent[®] and for 1 week after the last dose. Talk to your healthcare provider about the best way to feed your baby during treatment.

- Before you start use it

Tell your healthcare provider about all of your medical conditions, including if you:

- have a history of diabetes or high levels of sugar in your blood
- have a history of skin rash, redness of skin, blistering of the lips, eyes or mouth, or skin peeling
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to

breastfeed

- Taking other medicines

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking Trezilent[®] with other medicines may affect the way Trezilent[®] works and may cause side effects. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How to use Trezilent[®]

- How much to use

The recommended dose of Trezilent[®] is 300mg (two 150mg film-coated tablets) taken orally, once daily, with food.

- When to use it

Take Trezilent[®] 1 time each day, at about the same time each day. Take Trezilent[®] with food.

- How long to use it

Take Trezilent[®] for as long as your doctor tells you to do so.

This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long to take Trezilent[®] for, talk to your doctor or to your pharmacist.

- If you forget to use it

If you miss a dose of Trezilent[®], you may still take it with food up to 9 hours after the time you usually take it. If it has been more than 9 hours after you usually take your dose, skip the dose for that day. The next day, take the dose at your usual time. Do not take 2 doses to make up for a missed dose.

- If you use too much (overdose)

If you take too much Trezilent[®], call your healthcare provider or go to the nearest hospital emergency room right away.

While you are using it

- Things you must do

Swallow Trezilent® tablets whole. Do not chew, crush or split the tablets. If you vomit after taking a dose of Trezilent®, do not take another dose on that day. Take your next dose at your usual time.

- Things you must not do

Do not change your dose or stop taking Trezilent® unless your healthcare provider tells you.

Do not take any Trezilent® tablets that are broken, cracked, or that look damaged.

- Things to be careful of

Trezilent® may cause serious side effects, including:

- **Severe allergic reactions.** Tell your healthcare provider or get medical help right away if you have trouble breathing, swelling of the face or throat, flushing, rash, fever, or fast heart rate during treatment with Trezilent®.
- **Severe skin reactions.** Tell your healthcare provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, and swollen glands, with or without fever.
- **High blood sugar levels (hyperglycemia).** Hyperglycemia is common with Trezilent® and may be severe. Your healthcare provider will check your blood sugar levels and may give you a medicine called metformin before you start treatment with Trezilent®. Your healthcare provider will monitor your blood sugar levels during treatment and may monitor your blood sugar levels more often if you have a history of Type 2 diabetes. Tell your healthcare provider right away if you develop symptoms of hyperglycemia, including:
 - excessive thirst
 - dry mouth
 - more frequent urination than usual or a higher amount of urine than normal
 - increased appetite with weight loss
 - confusion
 - nausea
 - vomiting

- fruity odor on breath
- difficulty breathing
- dry or flushed skin

- **Lung problems (pneumonitis).** Tell your healthcare provider right away if you develop new or worsening symptoms of lung problems, including:
 - shortness of breath or trouble breathing
 - cough
 - chest pain
- **Diarrhea or colitis (inflammation of your intestines).** Diarrhea is common with Trezilent® and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Tell your healthcare provider right away if you develop diarrhea, stomach-area (abdominal) pain, or see mucus or blood in your stool during treatment with Trezilent®. Your healthcare provider may tell you to drink more fluids or take medicines to treat diarrhea or colitis.

Your healthcare provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with Trezilent® if you get certain serious side effects.

Do not use Trezilent® for a condition for which it was not prescribed.

Do not give Trezilent® to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about Trezilent® that is written for health professionals.

Side effects

The most common side effects of Trezilent® when used with fulvestrant include:

- Rash
- Nausea
- Tiredness and weakness
- Decreased appetite
- Mouth sore
- Vomiting
- Weight loss
- Hair loss
- Changes in certain blood test

Tell your healthcare provider right away if you develop any changes in your vision,

eye pain, sensitivity to light, or if your eyes look different.

Trezilent® 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 of the possible side effects of Trezilent®.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Trezilent®

Storage

- Keep out of the reach and sight of children.
- Do not take this medicine after the expiry date, which is stated on the box.
- Store in the original package.
- Store below 30 °C.
- Protect from moisture.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Trezilent® is supplied as film-coated tablets in aluminum blisters.

Film-coated tablets: 50 mg, 150 mg and 200 mg alpelisib

- 50 mg: Light pink, unscored, round and curved with beveled edges film-coated tablet, imprinted with “L7” on one side and “NVR” on the other side. Each film coated tablet contains 50 mg of alpelisib.
- 150 mg: Pale red, unscored, ovaloid and curved with beveled edges film-coated tablet, imprinted with “UL7” on one side and “NVR” on the other side. Each film coated tablet contains 150 mg of alpelisib.
- 200 mg: Light red, unscored, ovaloid and curved with beveled edges film-coated tablet, imprinted with “YL7” on one side and “NVR” on the other

side. Each film coated tablet contains 200 mg of alpelisib.

Serial Number
NPRA (R1/4)02072024/128

Packaging

300mg daily dose:

Pack of 14-day supply of 28 tablets (28 tablets, 150mg alpelisib per tablet)

250mg daily dose:

Pack of 14-day supply of 28 tablets (14 tablets, 200mg alpelisib per tablet and 14 tablets, 50mg alpelisib per tablet)

200mg daily dose:

Pack of 14-day supply of 14 tablets (14 tablets, 200mg alpelisib per tablet)

Ingredients

- Active ingredient

The active substance of Trezilent® is alpelisib.

- Inactive ingredients

Tablet core: Microcrystalline cellulose, mannitol, sodium starch glycolate, hypromellose, and magnesium stearate.

Coating material: Hypromellose, titanium dioxide, macrogol / polyethylene glycol (PEG), talc, iron oxide red, and iron oxide black.

MAL number(s):

Trezilent® 50 mg film-coated tablet:

MAL20076006ARZ

Trezilent® 150 mg film-coated tablet:

MAL20076007ARZ

Trezilent® 200 mg film-coated tablet:

MAL20076008ARZ

Manufacturer

Novartis Pharma Stein AG,
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Product Registration Holder

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