



Verzenio[®]
abemaciclib
50 | 100 | 150 mg tablets

A Lilly Medicine

WELCOME TO
VERZENIO



Whether you're newly
diagnosed or just starting
treatment, this brochure
can help you
learn more about Verzenio

TABLE OF CONTENTS

3	About Verzenio
4	Results with Verzenio + hormone therapy
6	Taking Verzenio
7	Common questions
9	How Verzenio + hormone therapy works
11	Side effects
14	Savings and support
17	Indication and Safety Summary



About Verzenio

What is Verzenio?

Verzenio is a prescription medicine used in combination with endocrine (hormone) therapy (tamoxifen or an aromatase inhibitor) to treat adults with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2–), node-positive, early breast cancer with a high risk of coming back as determined by your healthcare provider.

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

Verzenio is not chemotherapy

Verzenio has already treated 16,000 patients in the US with certain types of HR+, HER2– metastatic breast cancer. Verzenio + hormone therapy is **FDA approved** to treat patients with HR+, HER2–, node-positive, early breast cancer with a high risk of recurrence.

SELECT SAFETY INFORMATION

Warnings - Verzenio may cause serious side effects, including:

Diarrhea is common with Verzenio, may sometimes be severe and may cause dehydration or infection. The most common time to develop diarrhea is during the first month of Verzenio treatment. If you develop diarrhea during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it, stop your treatment, or decrease your dose.

If you have any loose stools, start taking an antidiarrheal medicine (such as loperamide), drink more fluids, and tell your healthcare provider right away.

Results with Verzenio + hormone therapy

Verzenio + hormone therapy is specifically for women with HR+, HER2–, node-positive early breast cancer with a high chance of returning, as determined by a healthcare provider.

Verzenio was studied in a clinical trial of 5637 adults with HR+, HER2–, node-positive, early breast cancer with a high chance of returning who had previously received primary treatment. In this study, 2808 patients were treated with Verzenio plus standard hormone therapy for 2 years, and then hormone therapy alone; 2829 patients received standard hormone therapy alone. The approval was based on a smaller group of 5120 patients from this study.

In this clinical study, Verzenio + hormone therapy was evaluated in people with HR+, HER2– early breast cancer with a high risk of recurrence based on extent of nodal involvement, tumor size, and tumor grade.

In a 4-year evaluation, Verzenio + hormone therapy showed a lower risk of cancer recurrence beyond the 2-year treatment period compared to hormone therapy alone.

35%
RISK ↓
reduction

Verzenio + hormone therapy showed a **35% reduction in the risk of cancer** returning compared with hormone therapy alone.

In a study, 85.5% of people taking Verzenio 150 mg by mouth twice daily + hormone therapy were alive without their cancer returning vs 78.6% taking hormone therapy alone. Data was assessed at 48 months; the study is ongoing to see if there is a survival benefit.

SELECT SAFETY INFORMATION

Warnings - Verzenio may cause serious side effects, including:

Low white blood cell counts (neutropenia) are common with Verzenio and may cause serious infections that can lead to death. Your healthcare provider should check your white blood cell counts before and during treatment. If you develop low white blood cell counts during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it, decrease your dose, or wait before starting your next month of treatment. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.

Taking Verzenio

How to take Verzenio + hormone therapy

Verzenio is taken every day, twice a day, for only 2 years unless your doctor tells you otherwise.

The recommended dose of Verzenio in combination with hormone therapy is 150 mg by mouth twice a day, taken once in the morning and once at night.



- Each pack contains your dose of 150-mg tablets for 7 days (14 individual 150-mg tablets)
- Multiple tablet strengths (50 mg, 100 mg, and 150 mg) allow your doctor to make dose adjustments based on how you tolerate the drug
- No matter what dose is prescribed, you will take 1 tablet, 2 times a day, unless your doctor tells you otherwise

SELECT SAFETY INFORMATION

Warnings - Verzenio may cause serious side effects, including:

Verzenio may cause severe or life-threatening inflammation (swelling) of the lungs during treatment that can lead to death. If you develop lung problems during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it, decrease your dose, or stop your treatment. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

- Trouble breathing or shortness of breath
- Cough with or without mucus
- Chest pain

Common questions about taking Verzenio

How often should I take Verzenio?



AM/PM

Take each dose of Verzenio by mouth 2 times daily—once in the morning and once in the evening—unless your doctor tells you otherwise.



Same times
every day

Try to establish a routine of taking your morning and evening doses at about the same times each day—for example, when you brush your teeth in the morning and before bed.



As directed
by your doctor

Take Verzenio exactly as your doctor tells you. Your doctor may change your dose if needed. Do not stop taking Verzenio or change the dose without talking to your doctor.

What should I do if I miss a dose or get sick after taking a dose?

If you vomit or miss a dose of Verzenio, take your next dose at your regular time. Do not take an extra dose of Verzenio to make up for any dose you may have missed.

- For example, if you forget to take your morning dose, then you should only take your regular evening dose rather than doubling it

SELECT SAFETY INFORMATION

Warnings - Verzenio may cause serious side effects, including:

Verzenio can cause serious liver problems. Your healthcare provider should do blood tests to check your liver before and during treatment. If you develop liver problems during treatment with Verzenio, your health care provider may reduce your dose or stop your treatment. Tell your healthcare provider right away if you have any of the following signs or symptoms of liver problems:

- Feeling very tired
- Loss of appetite
- Pain on the upper right side of your stomach area (abdomen)
- Bleeding or bruising more easily than normal

How should I take Verzenio?



- Swallow the prescribed number of Verzenio tablets whole. Do not chew, crush, or split before swallowing
- You can take Verzenio with or without food
- Avoid grapefruit and grapefruit products while taking Verzenio. Grapefruit may increase the amount of Verzenio in your blood

Can other medicines affect Verzenio?



- Verzenio and certain other medicines can affect each other, causing serious side effects or changing the effect of Verzenio or other medications
- Before starting any medication, make sure you talk to your doctor about all your other medications. Some examples include prescription and over-the-counter medicines, vitamins, and herbal supplements. Your doctor may need to change your dose



We are here for you as you start Verzenio.
If you have questions, please call 1-800-LillyRx (1-800-545-5979).

SELECT SAFETY INFORMATION

Warnings - Verzenio may cause serious side effects, including:

Verzenio may cause blood clots in your veins, or in the arteries of your lungs. Verzenio may cause serious blood clots that have led to death. If you develop blood clots during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it. Tell your healthcare provider right away if you have any of the following signs and symptoms of a blood clot:

- Pain or swelling in your arms or legs
- Fast heart rate
- Fast breathing
- Chest pain
- Shortness of breath

How Verzenio + hormone therapy works

Verzenio is a CDK4 & 6 inhibitor used to treat HR+, HER2-, node-positive, early breast cancer with a high risk of coming back as determined by your healthcare provider*

Verzenio works to block specific proteins called CDK4 & CDK6

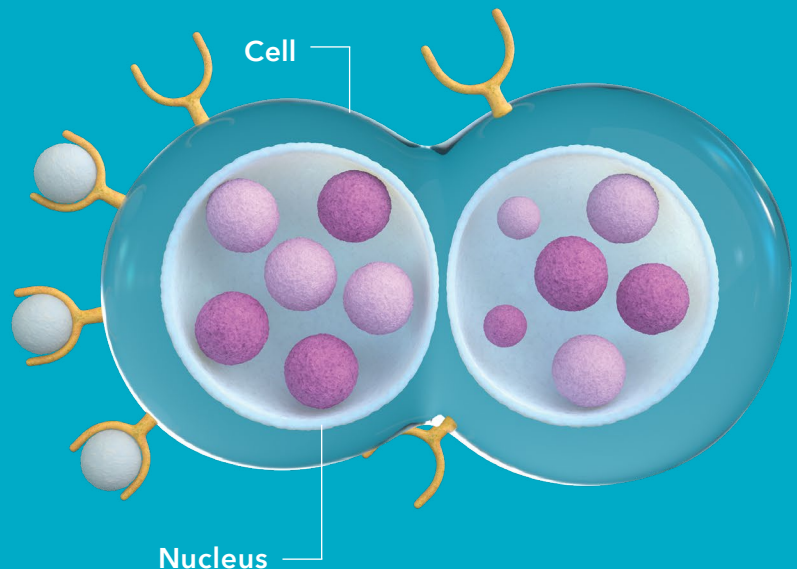
CDK4 & 6 proteins help control how fast cells grow



before

1.
These proteins, along with hormones like estrogen, play an important role in the growth and division process of normal cells.

2.
But if you have HR+, HER2- early breast cancer, CDK4 & 6 proteins become overactive, causing the cancer cells to grow and divide uncontrollably, which makes the tumor grow.



*Verzenio is taken after active therapy.

How Verzenio + hormone therapy works (*continued*)

Verzenio is a CDK4 & 6 inhibitor used to treat HR+, HER2-, node-positive, early breast cancer with a high risk of coming back as determined by your healthcare provider*

Verzenio works to block specific proteins called CDK4 & CDK6

Verzenio is taken with hormone therapy to help prevent cancer recurrence after active treatment

after

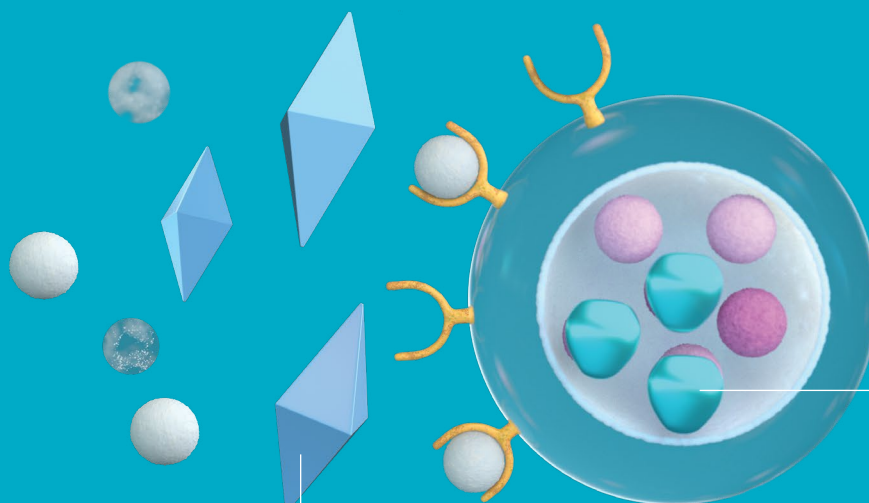


+



Hormone
therapy

Verzenio



1. Hormone therapy works **outside** the cell to reduce estrogen that feeds the cancer.

2. **Verzenio** works **inside** the cell to block CDK4 & 6 activity and help stop the growth of cancer cells.†

When **Verzenio** inhibits CDK4 & 6 in healthy cells, it can lead to side effects, some of which may be serious.

*Verzenio is taken after active therapy.
†Based on pre-clinical studies.

Side effects with Verzenio + hormone therapy

The most common side effects of taking Verzenio + hormone therapy:

- Diarrhea
- Low white blood cell counts (neutropenia, leukopenia)
- Nausea
- Infections
- Low red blood cell counts (anemia)
- Decreased appetite
- Headache
- Hair thinning or hair loss (alopecia)
- Abdominal pain
- Tiredness
- Vomiting
- Low platelet count (thrombocytopenia)



You should tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Verzenio.

For more information on managing side effects, see pages 12 and 13 of this brochure or ask your doctor, pharmacist, or nurse.

In a study of Verzenio + hormone therapy, it was common for patients to experience diarrhea that was sometimes severe. In some cases, it led to dehydration or infection. Diarrhea was greatest during the first month, and then decreased.



The median time to first symptoms was about 8 days (the median duration of moderate and more significant diarrhea was 6 and 5 days, respectively). However, some patients experienced this earlier or later in therapy.



The diarrhea was managed by their doctor with an anti-diarrheal medicine, like loperamide (sometimes sold under the brand name Imodium®), and/or by reducing the dose.* You should call your doctor right away if your diarrhea does not go away or gets worse.

*20% of patients required a dose interruption and 17% required a dose reduction.

SELECT SAFETY INFORMATION

Warnings - Verzenio may cause serious side effects, including:

Verzenio can harm your unborn baby. Use effective birth control (contraception) during treatment and for 3 weeks after the last dose of Verzenio and do not breastfeed during treatment with Verzenio and for at least 3 weeks after your last dose. Verzenio may affect the ability of males to father a child.

Most common side effects of Verzenio can be managed with a reduced dose.

The benefit of a reduced dose of Verzenio + hormone therapy is similar to that seen in adults receiving the recommended dose. Data from the clinical trial was further analyzed to assess the results when dose reduction was needed. These analyses were not pre-planned. Individual results may vary.

Take Verzenio exactly as your doctor tells you. Your doctor may change your dose if needed. Do not stop taking Verzenio or change the dose without talking to your doctor.

The recommended dose of Verzenio (in combination with hormone therapy) is 150 mg by mouth twice a day, taken once in the morning and once at night.

MyRightDose Exchange Program*

If your doctor recommends a change to your medication dosing, they can sign you up for a dose exchange program, at no cost to you. For educational purposes only. Consult with your healthcare provider for further details about the program. When used in combination with tamoxifen, or an aromatase inhibitor, the recommended dose of Verzenio® is 150 mg taken orally twice daily.

*Additional terms and conditions apply. Please talk with your doctor about program enrollment.

Verzenio
abemaciclib
50 | 100 | 150 mg tablets

A Lilly Medicine



SELECT SAFETY INFORMATION

Common side effects

The most common side effects of Verzenio include:

- Nausea
- Infections
- Low red blood cell counts (anemia)
- Decreased appetite
- Headache
- Hair thinning or hair loss (alopecia)
- Abdominal pain
- Tiredness
- Low white blood cell counts (leukopenia)
- Vomiting
- Low platelet counts (thrombocytopenia)

These are not all the possible side effects of Verzenio.

It is not known if Verzenio is safe and effective in children

Addressing diarrhea

The first step to managing side effects is to know what to expect.

Overall, the key information to know about diarrhea: it can be managed with the appropriate steps so **EXPECT, PLAN, and ACT.**

EXPECT: DIARRHEA IS A COMMON SIDE EFFECT

Diarrhea is a common side effect with Verzenio and may sometimes be severe, but you and your doctor can take steps to manage it. If diarrhea occurs, it will most likely happen in the first month. You should be on the lookout for cramping or frequent, loose, or watery stools.

PLAN: PLAN AHEAD OF TIME

It is important to plan ahead of time with your doctor. Make sure you have an over-the-counter anti-diarrheal medicine, such as loperamide (also known as Imodium®), available at home before you start taking Verzenio.

ACT: IMMEDIATE 24-HOUR ACTION PLAN

If you begin experiencing diarrhea, it is very important that you take action immediately at the first signs of symptoms. The best way to manage diarrhea is to start an antidiarrheal at the first sign and call your doctor, who may make a dose change.

SELECT SAFETY INFORMATION

Before using

Before you use Verzenio, tell your healthcare provider about all your medical conditions, including:

- If you have fever, chills, or other signs of infection.
- If you have a history of blood clots in your veins.
- Have lung or breathing problems.
- Have liver or kidney problems.
- If you are pregnant, plan to become pregnant, or are breastfeeding.
- About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take a medicine that contains ketoconazole.

Immediate 24-hour action plan



STEP 1: Start an antidiarrheal and call your doctor

If you are experiencing diarrhea, you need to start taking an antidiarrheal as directed on the packaging and call your doctor or nurse immediately so they are aware and can help you manage the diarrhea.



STEP 2: Stay hydrated and drink clear fluids

Drink at least 8-12 glasses of clear fluids in the first 24 hours you experience symptoms (and continue any day you experience diarrhea) to avoid dehydration.



STEP 3: Watch for improvement and follow up with your doctor

Ideally, the antidiarrheal will be able to help resolve your symptoms, but **if symptoms continue after the first 24 hours, you need to talk to your doctor or nurse that day.** He or she may consider adjusting your dose, with the ultimate goal of finding which dose is right for you. Verzenio is effective at different doses, so it is important to find what dose is right for your body.



Monitoring blood counts and liver function

Some patients experienced low white blood cell counts (neutropenia) and/or liver problems. Your doctor will do blood tests to monitor your blood cell counts and to check for liver problems before and during treatment.

Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088). You may also report side effects to Eli Lilly and Company at 1-800-545-5979.

SELECT SAFETY INFORMATION

How to take

- Take Verzenio exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose if needed. Do not stop taking Verzenio or change the dose without talking to your healthcare provider.
- Verzenio may be taken with or without food.
- Swallow Verzenio tablets whole. Do not chew, crush, or split the tablets before swallowing. Do not take Verzenio tablets if they are broken, cracked, or damaged.
- Take your doses of Verzenio at about the same time every day.
- If you vomit or miss a dose of Verzenio, take your next dose at your regular time. Do not take 2 doses at the same time to make up for the missed dose.

Savings and support resources

See how you can save on treatment and get support along the way.

Personalized care that's here for you

Lilly Support Services™ for Verzenio® offers various resources, ranging from helping you get started on Verzenio to connecting you with tools and information throughout your treatment. For personalized support throughout your journey with Verzenio, enroll in Lilly Support Services, where a Companion in Care™ can help you every step of the way.



The Lilly Support Services for Verzenio team, including the Companion in Care, is not made up of medical professionals. Your doctor is your source for medical advice.

Through 1-on-1 check-ins, Lilly Support Services can support you by:

- Navigating you through the insurance process*
- Helping give you guidance during your treatment journey
- Identifying potential savings opportunities†
- Answering questions you may have about Verzenio

Terms and conditions apply for all programs. See enrollment form for details.

*Lilly Support Services™ for Verzenio® is not a guarantee of coverage.

†Governmental beneficiaries excluded. Terms and conditions apply

3 simple ways to join

1
Enroll at
verzenio.lilly.com/support

or

2
Call
1-800-LillyRx
(1-800-545-5979)

or

3
Ask a member of your
healthcare team about
signing up

SELECT SAFETY INFORMATION

What to avoid during treatment

- Avoid taking ketoconazole during treatment with Verzenio. Tell your healthcare provider if you take a medicine that contains ketoconazole
- Avoid grapefruit and products that contain grapefruit during treatment with Verzenio. Grapefruit may increase the amount of Verzenio in your blood

Savings Card

Paying for treatment shouldn't be an additional concern for you and your loved ones, so we've created the Verzenio Savings Card,* which may help eligible, commercially insured patients with coverage for Verzenio manage treatment costs.



Scan to learn more about how to potentially
save* and get support while on Verzenio

***Governmental beneficiaries excluded, terms and conditions apply.**

Visit verzenio.lilly.com/savings-support
for more information on the Verzenio Savings Card

Filling your prescription

There are several options for getting Verzenio, depending on your insurance. You may receive your medication from your hospital, your doctor, or from a specialty pharmacy.

Here's how a specialty pharmacy works with you to fill your Verzenio prescription:

- Your doctor sends your prescription to a specialty pharmacy
- The specialty pharmacy will call you to schedule a date and time to deliver your Verzenio medication
- They can also help assess your eligibility for the Verzenio Savings Card*

***Governmental beneficiaries excluded. Terms and conditions apply**

Support groups

Lilly Support Services™ for Verzenio® can help connect you with advocacy groups and provide you with the support you need.

There are many organizations that offer opportunities to connect in person or online for support. The following support groups can help you connect with other women who have a shared experience with early breast cancer:

- BreastCancer.org
- Cancer Support Community
- Living Beyond Breast Cancer® (LBBC)
- SHARE Cancer Support
- TOUCH Black Breast Cancer Alliance
- Unite for Her
- Young Survival Coalition® (YSC)
- Susan G. Komen®

Learn more at verzenio.lilly.com/support or call **Lilly Support Services for Verzenio at 1-800-LillyRx (1-800-545-5979)**.

These resources are independent of Eli Lilly and Company or Lilly USA, LLC. Lilly is not responsible for the content.

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INDICATION AND SAFETY SUMMARY

Verzenio® (ver-ZEN-ee-oh) is used to treat certain types of breast cancer known as HR+/HER2– (hormone receptor positive/human epidermal growth factor receptor 2 negative) breast cancer.

It is a medicine you can take if:

- You have node-positive early breast cancer that has a high risk of coming back as determined by your healthcare provider. Verzenio is given along with hormonal therapy to women and men.

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

Warnings - Verzenio may cause serious side effects, including:

Diarrhea is common with Verzenio, may sometimes be severe and may cause dehydration or infection. The most common time to develop diarrhea is during the first month of Verzenio treatment. If you develop diarrhea during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it, stop your treatment, or decrease your dose.

If you have any loose stools, start taking an antidiarrheal medicine (such as loperamide), drink more fluids, and tell your healthcare provider right away.

Low white blood cell counts (neutropenia) are common with Verzenio and may cause serious infections that can lead to death. Your healthcare provider should check your white blood cell counts before and during treatment. If you develop low white blood cell counts during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it, decrease your dose, or wait before starting your next month of treatment. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.

Verzenio may cause severe or life-threatening inflammation (swelling) of the lungs during treatment that can lead to death. If you develop lung problems during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it, decrease your dose, or stop your treatment. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

- Trouble breathing or shortness of breath
- Cough with or without mucus
- Chest pain

Verzenio can cause serious liver problems. Your healthcare provider should do blood tests to check your liver before and during treatment. If you develop liver problems during treatment with Verzenio, your healthcare provider may reduce your dose or stop your treatment. Tell your healthcare provider right away if you have any of the following signs or symptoms of liver problems:

- | | |
|---|--|
| • Feeling very tired | • Loss of appetite |
| • Pain on the upper right side of your stomach area (abdomen) | • Bleeding or bruising more easily than normal |

Verzenio may cause blood clots in your veins, or in the arteries of your lungs. Verzenio may cause serious blood clots that have led to death. If you develop blood clots during treatment with Verzenio, your healthcare provider may tell you to temporarily stop taking it. Tell your healthcare provider right away if you have any of the following signs and symptoms of a blood clot:

- | | |
|---|-------------------|
| • Pain or swelling in your arms or legs | • Fast breathing |
| • Shortness of breath | • Fast heart rate |
| • Chest pain | |

Verzenio can harm your unborn baby. Use effective birth control (contraception) during treatment and for 3 weeks after the last dose of Verzenio and do not breastfeed during treatment with Verzenio and for at least 3 weeks after your last dose. Verzenio may affect the ability of males to father a child.

INDICATION AND SAFETY SUMMARY (CONTINUED)

Common side effects

The most common side effects of Verzenio include:

- Nausea
- Infections
- Low red blood cell counts (anemia)
- Decreased appetite
- Headache
- Hair thinning or hair loss (alopecia)
- Abdominal pain
- Tiredness
- Low white blood cell counts (leukopenia)
- Vomiting
- Low platelet counts (thrombocytopenia)

These are not all the possible side effects of Verzenio.

Tell your healthcare provider if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before using

Before you use Verzenio, tell your healthcare provider about all your medical conditions, including:

- If you have fever, chills, or other signs of infection.
- If you have a history of blood clots in your veins.
- Have lung or breathing problems.
- Have liver or kidney problems.
- If you are pregnant, plan to become pregnant, or are breastfeeding.
- About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take a medicine that contains ketoconazole.

How to take

- Take Verzenio exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose if needed. Do not stop taking Verzenio or change the dose without talking to your healthcare provider.
- Verzenio may be taken with or without food.
- Swallow Verzenio tablets whole. Do not chew, crush, or split the tablets before swallowing. Do not take Verzenio tablets if they are broken, cracked, or damaged.
- Take your doses of Verzenio at about the same time every day.
- If you vomit or miss a dose of Verzenio, take your next dose at your regular time. Do not take 2 doses at the same time to make up for the missed dose.

What to avoid during treatment

- Avoid taking ketoconazole during treatment with Verzenio. Tell your healthcare provider if you take a medicine that contains ketoconazole
- Avoid grapefruit and products that contain grapefruit during treatment with Verzenio. Grapefruit may increase the amount of Verzenio in your blood

Learn more

Verzenio is a prescription medicine. For more information, call 1-800-545-5979 or go to verzenio.com.

This summary provides basic information about Verzenio but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Verzenio and how to take it. Your healthcare provider is the best person to help you decide if Verzenio is right for you.

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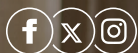


PERSONALIZED SUPPORT THAT'S HERE FOR YOU



To enroll, call **1-800-LillyRx**
(1-800-545-5979) or visit
verzenio.lilly.com/support

Visit the Verzenio Spanish website at
<https://verzenio.lilly.com/es>



SEARCH @VERZENIO OR VISIT

VERZENIO.LILLY.COM


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The Lilly Support Services for Verzenio team, including the Companion in Care, is not made up of medical professionals. Your doctor is your source for medical advice.

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