

Getting started with VIJOICE

The first and only targeted treatment for children and adults
with PIK3CA-Related Overgrowth Spectrum (PROS) conditions.

What is VIJOICE?

VIJOICE® (alpelisib) tablets is a prescription medicine used to treat adults and children 2 years of age and older with severe phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA)-Related Overgrowth Spectrum (PROS).

There are ongoing studies to confirm the benefit of VIJOICE.

It is not known if VIJOICE is safe and effective in children younger than 2 years of age.

IMPORTANT SAFETY INFORMATION

Do not take VIJOICE if you have had a severe allergic reaction to alpelisib or are allergic to any of the ingredients in VIJOICE.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

Not an actual patient



vijoice®
(alpelisib) tablets
50 mg | 125 mg | 200 mg

Minimize PROS.

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Maximize possibilities.

PROS is a part of your life. But sometimes it can feel like more than that. There are the struggles and frustrations of living with it every day. There are the many care teams, surgeries, and treatments that can relieve symptoms—but don't get to the source of your condition.

VIJOICE is a once-daily medication designed specifically for your condition and targets the underlying cause of PROS.

IMPORTANT SAFETY INFORMATION (cont)

VIJOICE may cause serious side effects, including:

- **Severe allergic reactions:** Tell your health care 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 VIJOICE

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What is PROS?

PIK3CA-Related Overgrowth Spectrum is the name for a group of conditions that is caused by a mutation in a gene called PIK3CA.

This mutation may lead to the gene not working like it's supposed to work.



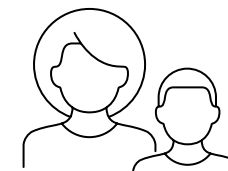
PROS includes:

- **KTS** (Klippel-Trenaunay Syndrome)
- **CLOVES syndrome** (Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal)
- **ILM** (Isolated Lymphatic Malformation)
- **MCAP (or M-CM)** (Megalencephaly-Capillary Malformation)
- **Macroductyly**
- **HME** (HemiMegalEncephaly)/**DMEG** (Dysplastic MEGalencephaly)/**Focal cortical dysplasia type II**
- **HHML** (HemiHyperplasia-Multiple Lipomatosis)
- **FIL** (Facial Infiltrating Lipomatosis)
- **FAVA** (FibroAdipose Vascular Anomaly)
- **Muscular HH** (HemiHyperplasia)
- **FAO** (FibroAdipose hyperplasia or Overgrowth)
- **CLAPO syndrome** (Capillary malformation of the lower lip, Lymphatic malformation of the face and neck, Asymmetry of the face and limbs, and Partial or generalized Overgrowth)
- **Epidermal nevus, benign lichenoid keratosis, or seborrheic keratosis**
- Other conditions may be identified and characterized as PROS

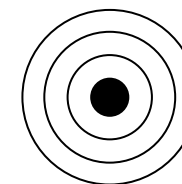
IMPORTANT SAFETY INFORMATION (cont)

- **Severe skin reactions:** Tell your health care provider or get medical help right away if you get a severe rash or a rash that keeps getting worse; reddened skin; flu-like symptoms; blistering of the lips, eyes, or mouth; blisters on the skin or peeling skin, with or without a fever
- **High blood sugar levels (hyperglycemia):** Hyperglycemia is common with VIJOICE and can be severe. Your health care provider will monitor your blood sugar levels before you start, and during treatment with, VIJOICE. Your health care provider may monitor your blood sugar levels more often if you have a history of diabetes.

What is VIJOICE?



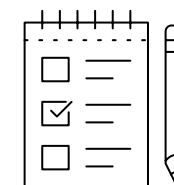
The first and only therapy approved to treat PROS in children and adults.



A targeted therapy

VIJOICE targets the underlying cause of PROS symptoms. It can also unintentionally affect healthy cells.

See more about the PIK3CA gene on page 6.



A treatment option for people with PROS that has safety and effectiveness results from studies in which treatment lasted at least 2 years and up to 6 years.

See pages 4 and 5 for more information about the EPIK-P1 and EPIK-P3 studies.

ViJOICE
(alpelisib) tablets
50 mg | 125 mg | 200 mg

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

VIJOICE may help with overgrowths

In EPIK-P1, the "initial study" of VIJOICE® in people* living with PROS, VIJOICE reduced the size of overgrowths in some people. It also helped with other PROS symptoms also associated with a mutation in the PIK3CA gene.



More than
1 in 4
(10/37)

saw meaningful reduction† in the size of their overgrowths at the 6-month evaluation.

These people had imaging scans to confirm reductions of at least 20%.
These reductions had to be seen in at least 2 scans in a row to be confirmed.

*The safety and effectiveness of VIJOICE were studied in 57 adults and children ages 2 years and older with CLOVES syndrome, MCAP (or M-CM), KTS, FIL, and other PROS conditions. All of the people in the study had a PIK3CA mutation confirmed by their doctor.

†A reduction of overgrowth size by at least 20%.

Minimize overgrowths.

Maximize opportunities.

IMPORTANT SAFETY INFORMATION (cont)

High blood sugar levels (hyperglycemia) (cont): Tell your health care provider right away if you develop symptoms of hyperglycemia, including excessive thirst, dry mouth, urinating more often than usual or having a higher amount of urine than normal, increased appetite with weight loss, confusion, nausea, vomiting, fruity odor on breath, difficulty breathing, or dry or flushed skin

- **Lung problems (pneumonitis):** Tell your health care provider right away if you develop new or worsening symptoms of lung problems, including shortness of breath or trouble breathing, cough, or chest pain

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Not an actual patient

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5

VIJOICE may also help with other PROS symptoms

The initial study was extended up to 6 years with 48 of the original 57 participants. In EPIK-P3, the "longer-term study," people who were treated with VIJOICE:



87%

(20/23)

felt less pain



(35/38)

experienced improvement

in issues caused by

vascular malformations



100%

(42/42)

felt less tired



86.2%

(25/29)

saw improvement in
limb asymmetry

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IMPORTANT SAFETY INFORMATION (cont)

- **Diarrhea or colitis (inflammation of your intestines):** Diarrhea is common with VIJOICE and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Tell your health care provider right away if you develop diarrhea or stomach-area (abdominal) pain, or see mucus or blood in your stool during treatment with VIJOICE. Your health care provider may tell you to drink more fluids or take medicines to treat diarrhea or colitis

Your health care provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with VIJOICE if you get certain serious side effects.

Minimize discomfort.

Maximize delight.

For a complete list of clinical results, please visit [VIJOICE.com](https://www.vijoice.com)

Not actual patients

It all starts with the PIK3CA gene

The PIK3CA gene provides instructions for how to make the protein phosphatidylinositol-3-kinase alpha, also referred to as PI3K α . This protein tells your cells when it's time to divide and grow. But a mutation (an abnormal change) in the PIK3CA gene can lead to it producing PI3K α proteins that don't know when to stop. So this faulty PIK3CA gene just keeps telling the affected cells to grow and grow and grow.

How a PIK3CA mutation leads to PROS

A mutation in the PIK3CA gene is at the root of all **13+ conditions called PROS**. (See more about these conditions on page 3.)

The mutation starts before birth and can happen anywhere in the body. This means everyone's symptoms are unique to them.

Most symptoms fall into these categories: **overgrowths, vascular malformations, and lymphatic malformations.**

Categories of PROS symptoms:



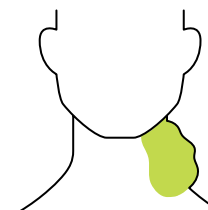
Overgrowths

When affected parts of the body—limbs, fingers, the head, anywhere, really—grow too much.



Vascular malformations

When there's abnormal structure of your veins, arteries, and/or capillaries. This can cause your blood flow to be too fast or too slow. If this affects the skin, it often appears as a "wine" spot or rash.



Lymphatic malformations

When there is abnormal development of the lymphatic system—channels where your body stores lymph, an important part of the immune system.

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Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

IMPORTANT SAFETY INFORMATION (cont)

Before you take VIJOICE, tell your health care provider about all your medical conditions, including if you:

- have a history of diabetes
- have a history of skin rash, redness of skin, blistering of the lips, eyes, or mouth, or peeling skin
- are pregnant or plan to become pregnant. VIJOICE can harm your unborn baby

Please see Important
Safety Information
throughout and click
here for full Prescribing
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Lymphatic malformation



Vascular malformation



Not actual patients

Overgrowth

How VIJOICE works

The PIK3CA gene makes a number of proteins, including the PI3K α protein. This protein plays a key role in telling your cells when to grow and divide. It also sends signals to regulate how other proteins function throughout your body.

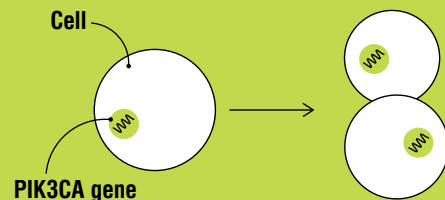
To explain the underlying cause of PROS and how VIJOICE works, let's focus on this relationship:

The **PIK3CA gene** makes **PI3K α proteins**, which send **growth signals**.

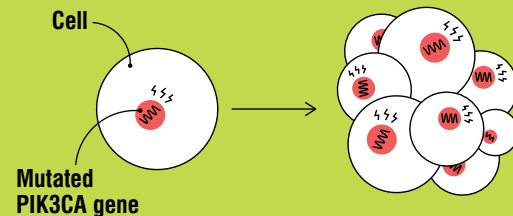


PROS includes more than 13 different conditions, but they all share the same underlying cause: a mutation in the PIK3CA gene.

Cell division is a normal, healthy process that helps your body grow.

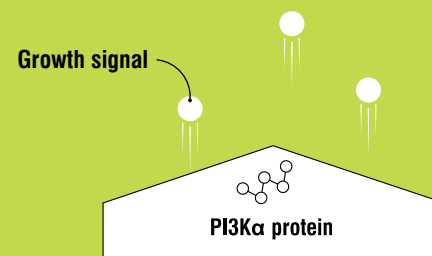


But a mutation (abnormality) in the PIK3CA gene can cause your cells to grow and divide too much. This PIK3CA mutation causing too much growth is the underlying cause of your PROS condition.

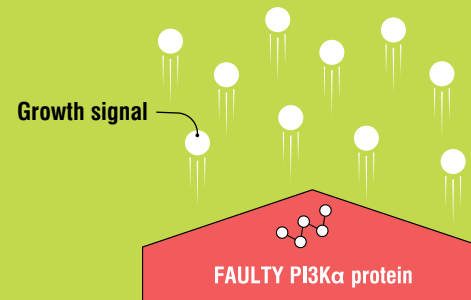


WHAT'S GOING ON INSIDE THE CELL

When functioning properly, the PI3K α protein sends a steady stream of growth signals, which results in normal division and growth of cells.

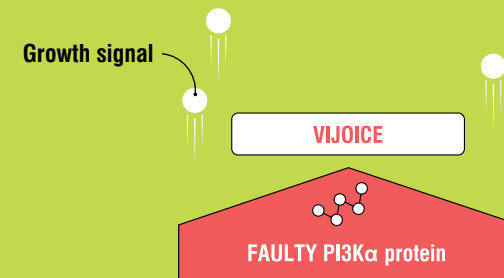


But a mutated PIK3CA gene creates a faulty PI3K α protein that consistently sends out too many growth signals, resulting in excessive cell division and growth.



VIJOICE can help slow down the signaling.

VIJOICE blocks extra growth signals sent by this faulty PI3K α protein before they can lead to too much cell division and growth. Slowing down the excess cell division helps reduce the symptoms of PROS—while still allowing normal cell growth.



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IMPORTANT SAFETY INFORMATION (cont)

- are breastfeeding or plan to breastfeed. It is not known if VIJOICE passes into your breast milk. Do not breastfeed during treatment with VIJOICE and for 1 week after the last dose
- Females who can become pregnant:**
 - Your health care provider will check to see if you are pregnant before you start treatment with VIJOICE
 - You should use effective birth control during treatment with VIJOICE and for 1 week after the last dose. Talk to your health care provider about birth control methods that may be right for you during this time

How to take VIJOICE

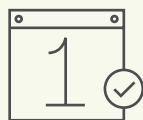
VIJOICE is a once-daily medication that comes in 2 forms: tablet(s) or individual oral granules packet. For instructions on how to take VIJOICE tablets, see page 10.

For instructions on how to take VIJOICE oral granules packet, see page 11.

Read the Instructions for Use carefully before taking or giving VIJOICE tablets and oral granules.

Talk to your health care provider or pharmacist if you have any questions. You can also call Novartis Pharmaceuticals Corporation at 1-888-845-6423 for more information.

VIJOICE should be taken:



Once a day



At the same
time each day



With food

Each blister pack and oral granules packet of VIJOICE contains your recommended full daily dose to help ensure you take the right dose at the right time—every time.

IMPORTANT SAFETY INFORMATION (cont)

- If you become pregnant or think you are pregnant, tell your health care provider right away

Males with female partners who can become pregnant should use condoms and effective birth control during treatment with VIJOICE and for 1 week after the last dose. If your female partner becomes pregnant, tell your health care provider right away.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VIJOICE and other medicines may affect each other and cause side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

50-mg, 125-mg, or 250-mg VIJOICE tablets



Important information you need to know before taking or giving VIJOICE tablets

- Take or give VIJOICE exactly as your health care provider tells you.
- **Do not** change your dose or stop taking VIJOICE unless your health care provider tells you.
- Take VIJOICE 1 time each day, at about the same time each day.
- Take VIJOICE with food.
- **Do not** combine VIJOICE tablets with VIJOICE oral granules to prepare your prescribed dose.
- If you miss a dose of VIJOICE, you may 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 vomit after taking a dose of VIJOICE, **do not** take another dose on that day. Take your next dose at your usual time.
- If you take too much VIJOICE, call your health care provider or go to the nearest hospital emergency room right away.

Storing VIJOICE tablets

- Store VIJOICE tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep VIJOICE and all medicines out of the reach of children.

Vijoice
(alpelisib) tablets
50 mg | 125 mg | 200 mg

**Please see additional
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50-mg, 125-mg, or 250-mg VIJOICE tablets

Preparing and taking or giving VIJOICE tablets

You can take or give VIJOICE tablets whole by mouth, or mixed with water (suspension) by mouth or through a feeding tube as described below and on the following pages:

Taking or giving VIJOICE tablets whole by mouth

Swallow VIJOICE tablets whole. Take with food.

- **Do not** chew, divide, or crush the tablets.
- **Do not** take VIJOICE tablets that are broken, cracked, or that look damaged.

Taking or giving VIJOICE tablets mixed with water (suspension) by mouth

If you cannot swallow tablets whole, VIJOICE tablets can be prepared as a suspension and taken or given by mouth.

Gather the following supplies (see Figure A):

- the number of VIJOICE tablet(s) needed for your prescribed dose
- water
- a clean empty cup
- a spoon

Figure A



50-mg, 125-mg, or 250-mg VIJOICE tablets

Taking or giving VIJOICE tablets mixed with water (suspension) by mouth (cont)

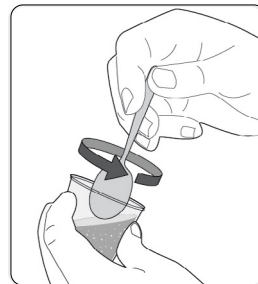
Step 1. Wash and dry your hands.

Step 2. Place VIJOICE tablets into a cup that contains 2 to 4 ounces of water. Use water only.

Step 3. Let the tablets stand in water **for about 5 minutes.**

Step 4. Crush the tablets with a spoon and stir to disperse the tablets in water (suspension). The suspension will be cloudy and you may see tablet particles (see **Figure B**).

Figure B



Step 5. Drink all of the suspension right away. If you cannot take or give it right away, take or give the suspension within 60 minutes of preparing the dose. Stir the suspension again with the same spoon before drinking it.

Step 6. Add about 1 to 2 ounces of water to the same cup and stir with the same spoon. Then drink all of the suspension to make sure the entire dose is taken.

Step 7. Repeat Step 6 until there are no tablet particles remaining in the cup.

Step 8. Wash your hands and all supplies used to take or give VIJOICE tablets.

Throw away any VIJOICE suspension that is not taken within 60 minutes after it is prepared.

50-mg, 125-mg, or 250-mg VIJOICE tablets

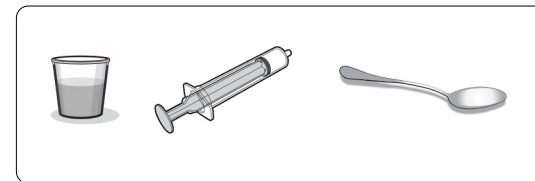
Giving VIJOICE tablets mixed with water (suspension) through a feeding tube

VIJOICE tablets may be given through a feeding tube, according to the manufacturer's instructions and as directed by your health care provider. **Only use silicone or polyurethane nasogastric tubes with a French size 5 to 12, or silicone gastric tubes with a French size 12 to 24.**

Gather the following supplies (see Figure C):

- the number of VIJOICE tablet(s) needed for your prescribed dose
- water
- a clean empty cup
- a spoon
- an enteral syringe

Figure C

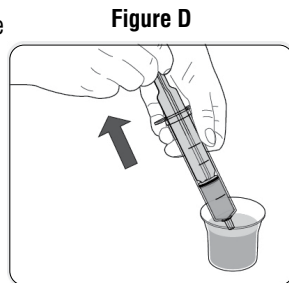


Please see next page for instructions on how to give VIJOICE tablets mixed with water (suspension) through a feeding tube.

50-mg, 125-mg, or 250-mg VIJOICE tablets

Giving VIJOICE tablets mixed with water (suspension) through a feeding tube (cont)

- Step 1.** Wash and dry your hands.
- Step 2.** Place VIJOICE tablets into a cup that contains 1 to 2 ounces (about 30 to 60 mL) of water. Use water only.
- Step 3.** Let the tablets stand in water **for about 5 minutes**.
- Step 4.** Crush the tablets with a spoon and stir to disperse the tablets in water (suspension). The liquid will be cloudy and you may see tablet particles (see **Figure B** on page 10).
- Step 5.** Draw up all of the suspension from the cup into an enteral syringe (see **Figure D**) and give it through the feeding tube right away. If you cannot give it right away, give the suspension within 60 minutes of preparing the dose. Stir the suspension again with the same spoon before drawing it up.
- Step 6.** Add about 1 to 2 ounces (about 30 to 60 mL) of water to the same cup and stir with the same spoon.
- Step 7.** Draw up all of the suspension into the same enteral syringe and give it through the feeding tube.
- Step 8.** Repeat Steps 6 and 7 if there are tablet particles remaining in the enteral syringe or in the cup.
- Step 9.** Wash your hands and all supplies used to give VIJOICE tablets. Follow the manufacturer's instructions to clean your enteral syringe.



Throw away any VIJOICE suspension that is not taken within 60 minutes after it is prepared.

50-mg VIJOICE oral granules packet

Important information you need to know before taking or giving VIJOICE oral granules

- Take or give VIJOICE exactly as your health care provider tells you.
- Do not** change your dose or stop taking VIJOICE unless your health care provider tells you.
- Take VIJOICE 1 time each day, at about the same time each day.
- Take VIJOICE with food.
- Each VIJOICE oral granules packet is for single use only.
- Do not** use the packet if the packet seal is broken.
- Do not** use multiple packets of 50 mg oral granules or part of a packet to prepare a dose.
- Do not** combine VIJOICE tablets with VIJOICE oral granules to prepare your prescribed dose.
- If you miss a dose of VIJOICE, you may 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 vomit after taking a dose of VIJOICE, **do not** take another dose on that day. Take your next dose at your usual time.
- If you take too much VIJOICE, call your health care provider or go to the nearest hospital emergency room right away.

Storing VIJOICE oral granules

- Store VIJOICE oral granules at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep VIJOICE and all medicines out of the reach of children.

50-mg VIJOICE oral granules packet

Preparing and taking or giving VIJOICE oral granules

You can take or give VIJOICE oral granules directly onto the tongue swallowed with water, or mixed with a beverage or soft food by mouth, or mixed with water through a feeding tube as described below and on the following pages:

Taking or giving VIJOICE oral granules directly onto the tongue

Gather the following supplies (see **Figure A**):

- 1 VIJOICE oral granules packet
- scissors
- water



Step 1. Wash and dry your hands.

Step 2. Hold the packet of oral granules with the cut line on top.

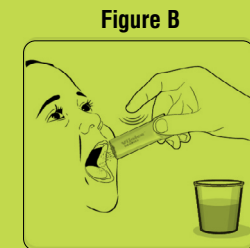
Step 3. Shake the packet gently to ensure the VIJOICE oral granules are in the lower part of the packet.

Step 4. Using scissors, open the packet along the cut line.

Step 5. Pour all the oral granules from 1 VIJOICE oral granules packet directly onto the tongue by tapping the side and top of the packet, and swallow it with about 2 to 4 ounces of water (see **Figure B**).

Step 6. If there is any medicine remaining in the mouth, rinse the mouth with additional water and swallow to make sure the entire dose is taken.

Step 7. Wash your hands and all supplies used to take or give VIJOICE oral granules.



50-mg VIJOICE oral granules packet

Taking or giving VIJOICE oral granules mixed with a beverage or soft food by mouth

Gather the following supplies (see Figure C):

- 1 VIJOICE oral granules packet
- scissors
- the beverage **or** soft food of your choice among water, milk, apple juice, applesauce, or yogurt. See Step 6.
- a clean empty cup
- a spoon

Figure C

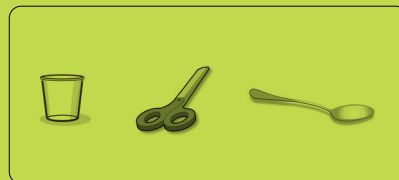


Figure D



Step 1. Wash and dry your hands.

Step 2. Hold the packet of oral granules with the cut line on top.

Step 3. Shake the packet gently to ensure the VIJOICE oral granules are in the lower part of the packet.

Step 4. Using scissors, open the packet along the cut line.

Step 5. Pour the oral granules from 1 VIJOICE oral granules packet into a cup by tapping the side and top of the packet (see Figure D).

50-mg VIJOICE oral granules packet

Taking or giving VIJOICE oral granules mixed with a beverage or soft food by mouth (cont)

Step 6. Add 1 to 3 teaspoons of a beverage (water, milk, or apple juice) or soft food (applesauce or yogurt), stir with a spoon, and take or give the mixture right away. If you do not take or give it right away, take or give the mixture within 60 minutes of preparing the dose. Stir the mixture with the same spoon before taking or giving it.

Step 7. Rinse the cup with up to 2 ounces of water, milk, or apple juice. Drink the rinse right away to make sure the entire dose is taken. Repeat this step until there are no oral granules remaining in the cup.

Step 8. Wash your hands and all supplies used to take or give VIJOICE oral granules.

Throw away any VIJOICE oral granules mixture that is not taken within 60 minutes after it is prepared.

Giving VIJOICE oral granules mixed with water (suspension) through a feeding tube

VIJOICE oral granules may be given through a feeding tube, according to the manufacturer's instructions and as directed by your health care provider. **Only use silicone or polyurethane nasogastric tubes with a French size 8 to 12, or silicone gastric tubes with a French size 12 to 24.**

Gather the following supplies (see Figure E):

- 1 VIJOICE oral granules packet
- water
- a clean empty cup
- a spoon
- an enteral syringe

Figure E



50-mg VIJOICE oral granules packet

Giving VIJOICE oral granules mixed with water (suspension) through a feeding tube (cont)

Step 1. Wash and dry your hands.

Step 2. Pour the oral granules from 1 VIJOICE oral granules packet into a cup by tapping the side and top of the packet (see Figure D).

Step 3. Add 4 teaspoons (about 20 mL) of water to the same cup and stir gently with a spoon to disperse the oral granules in the water (suspension). Use water only.

Step 4. Draw up all of the suspension from the cup into an enteral syringe (see Figure F) and give it through the feeding tube right away. If you cannot give it right away, give the suspension within 60 minutes of preparing the dose. Stir the suspension again with the same spoon before drawing it up.

Step 5. Add 4 teaspoons (about 20 mL) of water to the same cup and stir with the same spoon.

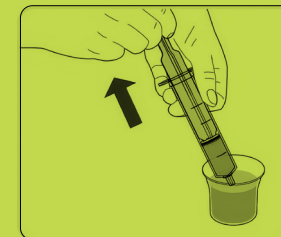
Step 6. Draw up all of the suspension from the cup into the same enteral syringe and give it through the feeding tube.

Step 7. Repeat Steps 5 and 6 until there are no oral granules remaining in the cup or in the syringe.

Step 8. Wash your hands and all supplies used to give VIJOICE oral granules. Follow the manufacturer's instructions to clean your enteral syringe.

Throw away any VIJOICE suspension that is not taken within 60 minutes after it is prepared.

Figure F





What should I do if I miss a dose, vomit, or have a side effect?

- If you miss a dose of VIJOICE, you may 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 vomit after taking a dose of VIJOICE, do not take another dose on that day. Take your next dose at your usual time.
- If a side effect occurs, your health care provider may reduce your dose, pause treatment, or have you stop taking VIJOICE.

IMPORTANT SAFETY INFORMATION (cont)

The most common side effects of VIJOICE include diarrhea, mouth sores (stomatitis), high blood sugar, headache, dry skin, and hair loss (alopecia).

VIJOICE may affect fertility in males and in females who can become pregnant. Talk to your health care provider if this is a concern for you.

These are not all the possible side effects of VIJOICE. Call your health care provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.



Not an actual patient

Vijoice[®]
(alpelisib) tablets
50 mg | 125 mg | 200 mg

For caregivers

Here are a few ways you can help the person you're caring for throughout treatment:



Set a daily routine

VIJOICE needs to be taken every day at the same time. Having the person take their tablet or tablets at breakfast time, before school or work, can help both of you stay on schedule. If they cannot swallow their pill, please follow the tips on page 10 for how to help them take it.



Recognize symptoms and side effects

It's not always easy for children to express how the condition or medication is making them feel, especially when they're very young. Learning how to recognize their signs, symptoms, and side effects can make sure they don't have to.



Don't be afraid to ask for help

Caregiving can feel overwhelming at times—especially if you're just starting out. There are other people and resources you can reach out to if you need any help.

Minimize exhaustion.

Maximize exploration.



Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

IMPORTANT SAFETY INFORMATION

Do not take VIJOICE if you have had a severe allergic reaction to alpelisib or are allergic to any of the ingredients in VIJOICE.

VIJOICE may cause serious side effects, including:

- **Severe allergic reactions:** Tell your health care 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 VIJOICE



Not actual patients

Potential side effects while taking VIJOICE

VIJOICE may cause side effects, so it's important to know what to expect and be prepared if side effects do occur.

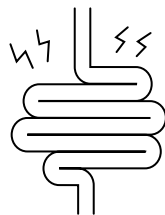
Some common side effects include:

- Diarrhea
- Dehydration
- Dry skin
- Headache
- High blood sugar
- Mouth sores
- Hair loss

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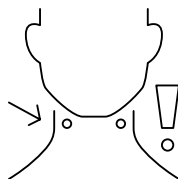
Please see Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

Be sure to let your doctor know right away if you start experiencing any of these serious side effects:



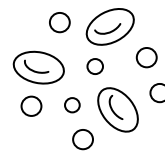
Diarrhea or colitis (inflammation of your intestines)

Diarrhea is common with VIJOICE and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Tell your doctor right away if you develop diarrhea or stomach-area (abdominal) pain or see mucus or blood in your stool during treatment with VIJOICE. Your doctor may tell you to drink more fluids or take medicines to treat diarrhea or colitis.



Severe allergic reactions

Tell your doctor or get medical help right away if you have trouble breathing, swelling of the face or throat, flushing, rash, fever, or a fast heart rate during treatment with VIJOICE.



High blood sugar levels (hyperglycemia)

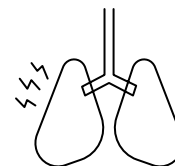
Hyperglycemia is common with VIJOICE and can be severe. Your doctor will monitor your blood sugar levels before you start, and during treatment with, VIJOICE. Your doctor may monitor your blood sugar levels more often if you have a history of diabetes. Tell your doctor right away if you develop symptoms 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



Severe skin reaction

Tell your doctor or get medical help right away if you get a severe rash or a rash that keeps getting worse; reddened skin; flu-like symptoms; blistering of the lips, eyes, or mouth; or blisters on the skin or peeling skin, with or without fever.



Lung problems (pneumonitis)

Tell your doctor right away if you develop new or worsening symptoms of lung problems, including:

- shortness of breath or trouble breathing
- cough
- chest pain



In the initial and longer-term studies, no participant discontinued treatment due to side effects.

Tell your doctor if you have any side effects that bother you or don't go away. Contact your doctor for medical advice about side effects.

In the studies, these side effects were reported as mild or moderate, with the exception of diarrhea, which was reported in all cases as mild. The serious side effects that were noted in multiple people were dehydration (2 people) and cellulitis, a type of skin infection (2 people). These are not all the possible side effects of VIJOICE.

Frequently asked questions

Can VIJOICE affect my child's natural growth?

With up to 6 years of treatment with VIJOICE in the longer-term study, there are no reports that it can affect children's natural growth as they age. In this study of the safety and effectiveness of VIJOICE, most children treated with VIJOICE experienced normal growth and development.

Does VIJOICE affect the immune system?

VIJOICE is the first and only medication that is FDA approved specifically to treat PROS conditions. A targeted treatment, VIJOICE does not suppress the immune system.

Is VIJOICE used to treat cancer?

No, it is not used to treat cancer. Alpelisib, the active ingredient in VIJOICE, is also in another medicine used to treat cancer, but it has different dosing. VIJOICE is not chemotherapy.

Did any serious side effects occur in multiple people taking VIJOICE?

In the initial and longer-term studies, dehydration and cellulitis (a type of skin infection) were the serious side effects reported by multiple people (dehydration in 2 people, cellulitis in 2 people).

Tell your doctor if you have any side effects that bother you or don't go away. Contact your doctor for medical advice about side effects.

Is having hyperglycemia the same as having diabetes?

It's important to understand the difference between hyperglycemia and diabetes.

- **Hyperglycemia** is high blood sugar—due to any cause. It is also a characteristic of having diabetes
- **Type 1 diabetes** is a condition in which your body stops making the insulin it needs to regulate blood sugar by allowing sugar in the blood to enter cells of the body
- **Type 2 diabetes** is a condition in which your body either does not make enough insulin or is unable to use it correctly

If you have a history of diabetes, talk to your doctor about how that might affect your treatment with VIJOICE.

In general, hyperglycemia that can be caused by VIJOICE is not the same as having diabetes.

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Important Safety
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IMPORTANT SAFETY INFORMATION (cont)

- **Severe skin reactions:** Tell your health care provider or get medical help right away if you get a severe rash or a rash that keeps getting worse; reddened skin; flu-like symptoms; blistering of the lips, eyes, or mouth; blisters on the skin or peeling skin, with or without a fever



Not actual patients

Financial resources & support

Starting a new treatment is a big step, but you're not taking it alone. **You have support to help you every step of the way.**

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Please see Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

Pay as little as **\$0 per month** for VIJOICE

 NOVARTIS



Universal Co-pay Card
Save on your out-of-pocket costs

To find out if you are eligible, call
1-877-577-7756, or visit
Copay.NovartisOncology.com

- Eligible patients with **private insurance may pay \$0 per month**
- Novartis will pay the remaining co-pay, up to \$15,000 per calendar year, per product*

To find out if you are eligible for the Universal Co-pay Program, call **1-877-577-7756**, visit **Copay.NovartisOncology.com**, or scan this QR code:



*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit Copay.NovartisOncology.com or call 1-877-577-7756.

Minimize Fatigue.
Maximize Fun.



Not actual patients

Glossary

PIK3CA-Related Overgrowth Spectrum (PROS)

A group of conditions in which one or more parts of the body grow at a faster rate than what is normal, and/or there are other irregularities in tissues within the body that cause deformities. PROS conditions are usually caused by an abnormal change in the PIK3CA gene.

PIK3CA Mutation

When the PIK3CA gene develops abnormally, the wrong instructions are given to your body to increase activity of the PI3K protein. When this gene is abnormal, it causes problems in certain cells and tissues in the body.

PI3K

This is a protein known as phosphatidylinositol-3-kinase. Its job is to make sure your cells grow and live correctly.



Please see Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

Overgrowth

This means a part of the body grows extra tissue and appears larger than it should. In PROS conditions, this can happen externally on the body, meaning it is visible under the skin, as well as internally with overgrowths of deep soft tissue. An overgrowth can be in one specific area or spread over parts of the body.

Vascular malformations/anomalies

Improper structure and connections of blood vessels, like your veins, for example.

Lymphatic malformations

Improper structure and connections of lymph vessels. These abnormal lymph vessels form spongy clumps which prevent fluids from flowing in the lymph vessel system.

Macroductyly

A kind of overgrowth that appears in your toes or fingers, making some bigger than the others.

Port-wine stains

An area that is both red and purple resulting from small blood vessel (capillary) malformations under the skin.

Scoliosis

Changes to the spine, which cause it to curve to one side.

Terms you may hear during appointments with your doctor:

Ablation

When a doctor removes a piece of body tissue during surgery.

Biopsy

A procedure in which your doctor removes a tiny sample of cells or tissues with surgical tools to be examined up close. Biopsies are done to confirm a diagnosis or to monitor changes in cells or tissues over time.

CT/CAT Scan

CT stands for computed tomography, and it is a type of imaging test. This procedure is like an X-ray and although it can take more time to perform, it gives doctors a more detailed image of the soft tissue, bones, and muscle inside the body.

MRI

This is short for magnetic resonance imaging, and it is a type of imaging test. MRI machines use radiating waves to take very detailed pictures of the inside of your body to help doctors understand what's happening inside of you. Taking these detailed pictures, which is often done to closely look at your soft tissue and organs, can take some time to perform.

Surgery

When doctors fix a problem inside the body by using cutting instruments to get to the area needing repair, and other tools to perform the repair. For example, joint replacement is a surgery in which doctors remove damaged bone and cartilage from the area where different bones meet each other and insert artificial pieces that replicate the original joint.

Ultrasound

This is an imaging test that doctors use to look inside the body, which is different from X-ray, CT scan, and MRI. The doctor uses a machine that bounces sound waves off of organs to create a picture of what is happening inside the body.

X-ray

An imaging test doctors use to take special pictures of the human body's internal composition, such as images of the bones.

Is there anything I should tell my other doctors about my treatment?

What are the potential side effects, and what should I do if I have any?

What kind of results might I see, and how soon might I see them after starting VIJOICE?



Please see Important Safety Information throughout and [click here](#) for full Prescribing Information, including Patient Information.

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Summary of Important Information

What is VIJOICE?

VIJOICE® (alpelisib) tablets is a prescription medicine used to treat adults and children 2 years of age and older with severe phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA)-Related Overgrowth Spectrum (PROS).

There are ongoing studies to confirm the benefit of VIJOICE.

It is not known if VIJOICE is safe and effective in children younger than 2 years of age.

Who should not take VIJOICE?

Do not take VIJOICE if you have had a severe allergic reaction to alpelisib or are allergic to any of the ingredients in VIJOICE.

What should I tell my health care provider before taking VIJOICE?

Before you take VIJOICE, tell your health care provider about all your medical conditions, including if you:

- have a history of diabetes
- have a history of skin rash, redness of skin, blistering of the lips, eyes, or mouth, or peeling skin
- are pregnant or plan to become pregnant. VIJOICE can harm your unborn baby

- are breastfeeding or plan to breastfeed. It is not known if VIJOICE passes into your breast milk. Do not breastfeed during treatment with VIJOICE and for 1 week after the last dose

Females who can become pregnant:

- Your health care provider will check to see if you are pregnant before you start treatment with VIJOICE
- You should use effective birth control during treatment with VIJOICE and for 1 week after the last dose. Talk to your health care 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 health care provider right away

Males with female partners who can become pregnant should use condoms and effective birth control during treatment with VIJOICE and for 1 week after the last dose. If your female partner becomes pregnant, tell your health care provider right away.

What other medications might interact with VIJOICE?

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VIJOICE and other medicines may affect each other and cause side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

What are the possible side effects of VIJOICE?

VIJOICE may cause serious side effects, including:

- **Severe allergic reactions:** Tell your health care 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 VIJOICE

- **Severe skin reactions:** Tell your health care provider or get medical help right away if you get a severe rash or a rash that keeps getting worse; reddened skin; flu-like symptoms; blistering of the lips, eyes, or mouth; blisters on the skin or peeling skin, with or without a fever
- **High blood sugar levels (hyperglycemia):** Hyperglycemia is common with VIJOICE and can be severe. Your health care provider will monitor your blood sugar levels before you start, and during treatment with, VIJOICE. Your health care provider may monitor your blood sugar levels more often if you have a history of diabetes. Tell your health care provider right away if you develop symptoms of hyperglycemia, including excessive thirst, dry mouth, urinating more often than usual or having a higher amount of urine than normal, increased appetite with weight loss, confusion, nausea, vomiting, fruity odor on breath, difficulty breathing, or dry or flushed skin
- **Lung problems (pneumonitis):** Tell your health care provider right away if you develop new or worsening symptoms of lung problems, including shortness of breath or trouble breathing, cough, or chest pain
- **Diarrhea or colitis (inflammation of your intestines):** Diarrhea is common with VIJOICE and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Tell your health care provider right away if you develop diarrhea or stomach-area (abdominal) pain, or see mucus or blood in your stool during treatment with VIJOICE. Your health care provider may tell you to drink more fluids or take medicines to treat diarrhea or colitis

Your health care provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with VIJOICE if you get certain serious side effects.

The most common side effects of VIJOICE include diarrhea, mouth sores (stomatitis), high blood sugar, headache, dry skin, and hair loss (alopecia).

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

These are not all the possible side effects of VIJOICE. Call your health care provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

What laboratory monitoring tests do I need when taking VIJOICE?

Your health care provider will monitor your blood sugar levels before you start, and during treatment with, VIJOICE. Your health care provider may monitor your blood sugar levels more often if you have a history of diabetes.

General information about the safe and effective use of VIJOICE

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

For more information about VIJOICE, talk with your health care provider or pharmacist. The FDA-approved product labeling or full Prescribing Information can be found at VIJOICE.com.

Please see additional Important Safety Information throughout.

To learn more about
VIJOICE® (alpelisib) tablets,
talk to your doctor
and visit [VIJOICE.com](https://www.vioice.com)



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