

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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Not an actual patient



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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** (**K**lippel-**T**renaunay Syndrome)
- **CLOVES syndrome** (**C**ongenital **L**ipomatous **O**vergrowth, **V**ascular malformations, **E**pidermal nevi, **S**coliosis/skeletal and spinal)
- **ILM** (Isolated **L**ymphatic **M**alformation)
- **MCAP** (or **M-CM**) (**M**egalencephaly-**C**apillary **M**alformation)
- **Macroductyly**
- **HME** (**H**emi**M**egal**E**ncephaly)/**DMEG** (**D**ysplastic **M**EGalencephaly)/**Focal cortical dysplasia type II**
- **HHML** (**H**emi**H**yperplasia-**M**ultiple **L**ipomatosis)
- **FIL** (**F**acial **I**nfiltrating **L**ipomatosis)
- **FAVA** (**F**ibro**A**dipose **V**ascular **A**nomaly)
- **Muscular HH** (**H**emi**H**yperplasia)
- **FAO** (**F**ibro**A**dipose hyperplasia or **O**vergrowth)
- **CLAPO syndrome** (**C**apillary malformation of the lower lip, **L**ymphatic malformation of the face and neck, **A**symmetry of the face and limbs, and **P**artial or generalized **O**vergrowth)
- **Epidermal nevus, benign lichenoid keratosis, or seborrheic keratosis**
- Other conditions may be identified and characterized as PROS

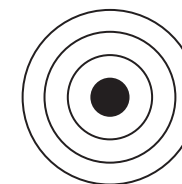
IMPORTANT SAFETY INFORMATION (cont)

- **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?



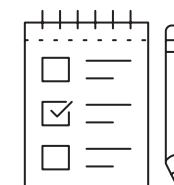
The first and only therapy approved to treat PROS in children and adults.



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.

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VIJOICE may help with overgrowths

In EPIK-P1, the "initial study" of VIJOICE® (alpelisib) tablets 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)

- 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

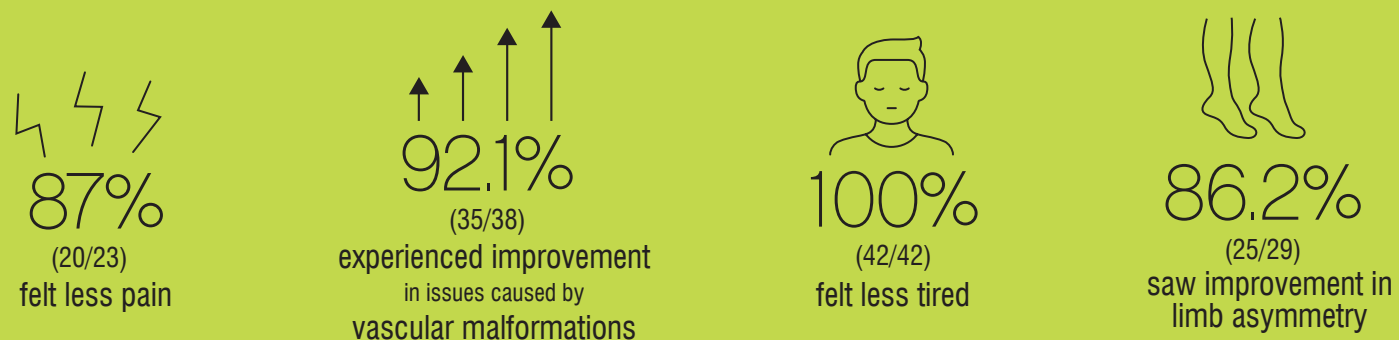
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Not an actual patient

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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:



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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**

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:



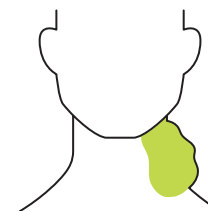
Overgrowths

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.

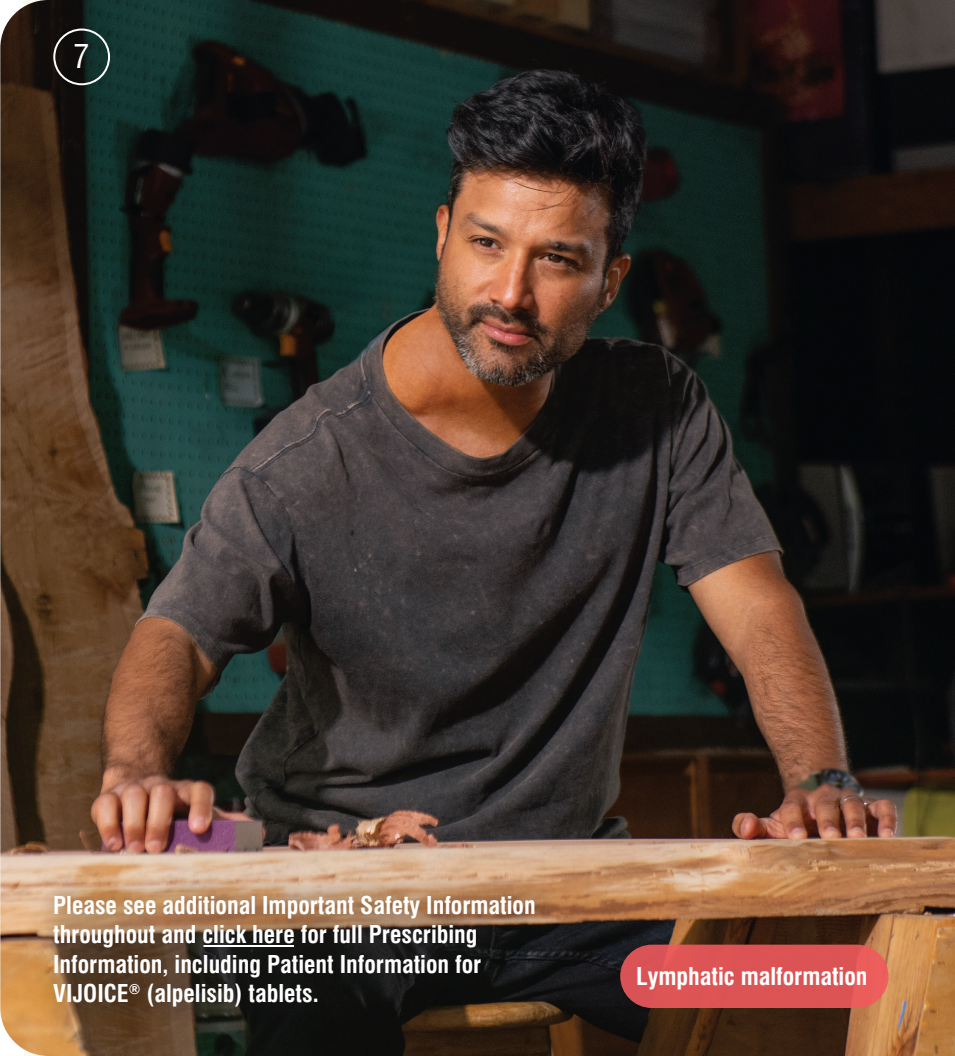
IMPORTANT SAFETY INFORMATION (cont)

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

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

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.

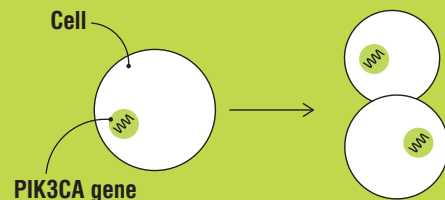
To explain the underlying cause of PROS and how VIJOICE works, let's focus on this relationship:

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

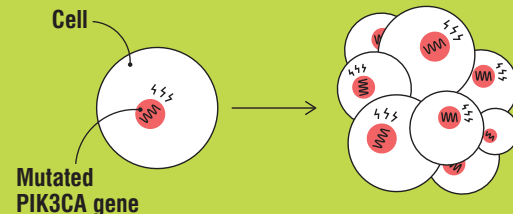


PROS includes more than 13 different conditions, but they all share the same underlying cause: a mutation in the PIK3CA gene.

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

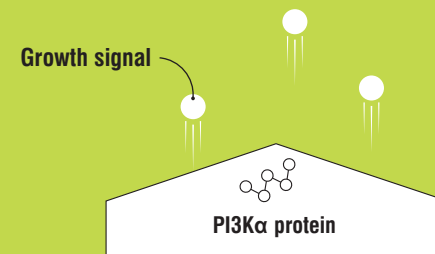


But a mutation (abnormality) in the PIK3CA gene can cause your cells to grow and divide too much. This PIK3CA mutation causing too much growth is the underlying cause of your PROS condition.

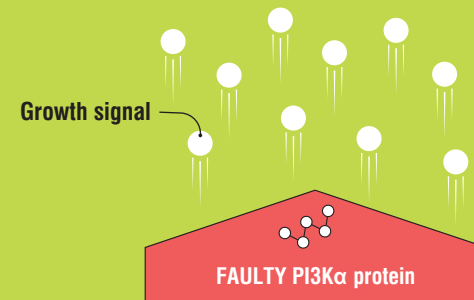


WHAT'S GOING ON INSIDE THE CELL

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

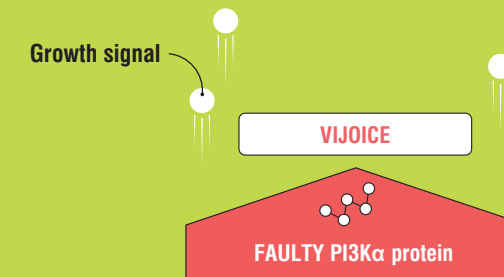


But a mutated PIK3CA gene creates a faulty PI3K α protein that consistently sends out too many growth signals, resulting in excessive cell division and growth.



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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Please see additional
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including **Patient
Information.**

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

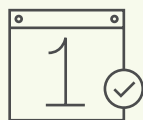
VIJOICE is a once-daily medication that comes in 2 forms: tablet(s) or individual granule packets.

For instructions on how to take VIJOICE tablets, see page 9.

For instructions on how to take VIJOICE granule packets, see page 10.

No matter the dose, remember to always follow your doctor's instructions.

VIJOICE should be taken:



Once a day



At the same
time each day



With food

Each blister pack and granule 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



If your doctor has prescribed VIJOICE tablets, you'll receive them in color-coded blister packs labeled with the days you're supposed to take each one.

If you are able to swallow tablets, please swallow VIJOICE tablets whole. Do not split or chew the tablets.

If you or the person you're caring for can't swallow VIJOICE

1. Place the VIJOICE tablets or tablet in a glass containing 2 to 4 ounces of water, and let it stand for about 5 minutes.
2. Crush the tablet or tablets with a spoon and stir to dissolve. The liquid will be cloudy, and you may see tablet pieces.
3. Drink the mixture right away.
4. After drinking the mixture, add about 1 to 2 ounces of water to the same glass. Stir with the same spoon, and drink the entire contents of the glass. Repeat this step if necessary.
5. Throw away any contents of the glass that are not consumed within 60 minutes after preparation.



Only use water while making this mixture

Please see page 10 for instructions on how to take VIJOICE granules.

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50 mg | 125 mg | 250 mg

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50-mg oral granule packets

In some cases, doctors may prescribe VIJOICE® (alpelisib) tablets in granule packets. Each packet is for single use only. No packet should be used if the packet seal is broken.

There are two ways to take your daily dose:

WITH WATER

1. Pour the contents of one VIJOICE oral granules packet directly onto the tongue and swallow with about 2 to 4 ounces of water.
2. If needed, use additional water to swish around and swallow. Repeat until no particles remain in the mouth.

WITH OTHER LIQUID OR SOFT FOOD

1. Pour the contents of one VIJOICE granule packet into a glass, cup, or bowl.
2. Add 1 to 3 teaspoons of a beverage (such as water, milk, or apple juice) or soft food (like applesauce or yogurt).
3. Stir or mix contents.
4. Drink or eat the mixture right away.
5. When finished, rinse the glass, cup, or bowl with up to 2 ounces of water, milk, or apple juice and drink the mixture immediately. Repeat this step until no granules remain.
6. Throw away the mixture if it is not consumed within 2 hours after preparation.

Do not use multiple packets or part of a packet of 50-mg oral granules to prepare a dose.

Do not combine VIJOICE tablets and oral granules to achieve the prescribed dose of 125 mg or 250 mg.



What should I do if I miss a dose?

If you miss a dose of VIJOICE, you can take it with food within 9 hours after the time it is usually taken. If it has been more than 9 hours, skip the dose for that day. The next day, take VIJOICE at the usual time.

If you vomit after taking the dose, do not take an additional dose on that day. Resume the dosing schedule the next day at the usual time. If a serious side effect occurs, your doctor 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

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 9 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.

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

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Vijoice
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50 mg | 125 mg | 200 mg

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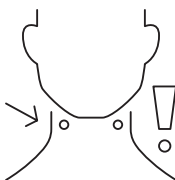
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Be sure to let your doctor know right away if you start experiencing any of these serious side effects:



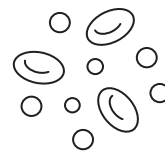
Diarrhea or colitis (inflammation of your intestines)

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)

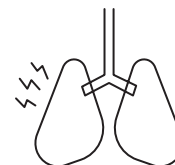
Hyperglycemia is common with VIJOICE and can be severe. Your doctor will monitor your blood sugar levels before you start, and during treatment with, VIJOICE. Your doctor may monitor your blood sugar levels more often if you have a history of diabetes. Tell your doctor right away if you develop symptoms 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 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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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
Copoly.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 Copoly.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 Copoly.NovartisOncology.com or call 1-877-577-7756.

There is also the **free trial and access program**

If you have been prescribed VIJOICE, you may be eligible to receive a free 28-day supply shipped directly to your home, with the possibility of obtaining 1 more free refill, which will allow you to start your treatment quickly.

No purchase of VIJOICE or any other product is required. This offering is for the approved indication only.



Ask your doctor to help you apply for the VIJOICE Free Trial and Access Program.

The VIJOICE VIP Program™

If you would like additional support throughout your treatment, you can enroll in the VIJOICE® (alpelisib) tablets VIP Program.



Navigate your insurance

The VIP Program can help you understand your insurance and provide information about financial assistance that may be available to you.



Find answers to your questions

You can get more information about VIJOICE, tips for fitting your treatment into your day-to-day life, and additional educational resources.

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

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 additional 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?



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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.vijoice.com)



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