# **VIJOICE** Talking to your doctor about treatment

This guide is designed to help you have productive conversations with your health care team.

# -VIJOICE contacts

Prescribing doctor:
Nurse:
Location:
Phone number:



# Getting ready for your next appointment

# Top tips for treatment

It's normal to have questions when starting a new treatment regimen. The following tips can help ensure you feel confident throughout your journey with VIJOICE:



#### Prepare for your appointments

Jot down appropriate questions to ask your doctor Communicate with your doctor if medication side effects are bothering you



#### Take notes during appointments

Bring a notebook or journal with you so you don't have to rely on remembering every important detail Writing things down will allow you to review important information after the appointment when you are back home



### **Check for refills**

When getting medication, check to see how many refills you have left

Set up reminders on your phone that notify you when you will be running low on medication

You can find answers to key questions about VIJOICE in the <u>Your Guide to</u> <u>Treatment With VIJOICE</u> brochure. But, you may have some additional or more specific questions to ask your prescribing doctor, such as the ones that follow. Jot the answers down in the available space for your reference.



## How do I take VIJOICE?

Write your answers here...

#### 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.



# Getting ready for your next appointment (cont)

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How long will I be on treatment?



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



#### **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.

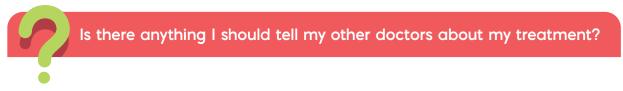
#### VIJOICE may cause serious side effects, including:

- 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
- 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

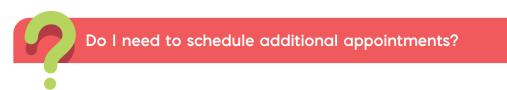




# Getting ready for your next appointment (cont)







#### **IMPORTANT SAFETY INFORMATION (cont)**

#### VIJOICE may cause serious side effects, including:

 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



# Getting ready for your next appointment (cont)

Additional notes for your prescribing doctor

Additional notes to share with your health care team

# Find a multidisciplinary team

The International Society for the Study of Vascular Anomalies (ISSVA) has created a list of multidisciplinary teams that treat vascular anomalies, which may be signs and features of PROS. ISSVA believes that a team environment is the best setting for managing the complex problems that arise when treating vascular anomalies.

To view the list of multidisciplinary care teams, visit **https://www.issva.org/resources/multidisciplinary-teams**.

Novartis does not provide or supervise medical care furnished through these treatment centers, which are independently owned and operated.

#### IMPORTANT SAFETY INFORMATION (cont)

#### VIJOICE may cause serious side effects, including:

- 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

**Vijoice** (alpelisib) tablets <sup>50 mg | 125 mg | 200 mg</sup>

# Who's who on your health care team?

# Types of health care teams

Depending on your situation, you may be treated in a **Vascular Anomalies Center** and/or by **individual doctors**.

A **Vascular Anomalies Center** is made up of multiple types of doctors, called a multidisciplinary team. These doctors collaborate and communicate together to treat and manage many parts of your PROS condition. The goal of this team is to provide you with the most comprehensive care possible

You may also see **individual doctors**, like a family pediatrician or internist, to manage the diverse symptoms of your PROS condition. Sometimes, these doctors are not connected with a multidisciplinary team, so you might see them in a one-on-one setting

In both of these settings, you may work with some or all of the following specialists. That's why it's important to understand their role in your treatment journey with VIJOICE. **Check the circles of the specialists you see,** and then ask the doctor who prescribed VIJOICE for you if there is anything you should share with them about your treatment experience.

# Pediatrician/internist

Responsible for your general health and may refer you to a feature-specific specialist



# Interventional radiologist

Performs procedures, such as radiologic embolization procedures; sclerotherapy; radiofrequency ablation, which uses heat to treat venous malformations; and aspiration, or the draining of excess fluid found in overgrowths

## More specialists are listed on the next page



#### **IMPORTANT SAFETY INFORMATION (cont)**

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.



# Who's who on your health care team? (cont)



Manages brain conditions, such as Megalencephaly-Capillary Malformation, or MCAP (or M-CM), and HemiMegalEncephaly/Dysplastic MEGalencephaly, or HME/DMEG, as well as developmental delays and other neurological complications in people with other PROS conditions, including Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal, or CLOVES syndrome

## Dermatologist

Manages the health of your skin, and may perform procedures to remove overgrowths and lesions in skin conditions, such as epidermal nevus, benign lichenoid keratosis, and seborrheic keratosis

## Hematologist/oncologist

Consulted for hematologic complications from vascular malformations, including lymphatic malformations, and for surgery



## Surgeon

Typically removes overgrowths. Types of surgical specialists include orthopedic surgeons, vascular surgeons, and neurosurgeons. Surgical and radiologic embolization procedures are currently the most common approaches to managing PROS. But, these procedures aren't right for everyone. Since it's common for overgrowths to return after surgery, repeat surgeries are frequently required

## More specialists are listed on the next page



#### **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



# Who's who on your health care team? (cont)

# Physical therapist

Helps with mobility issues and pain, which are common in people with PROS conditions

# Geneticist

Helps treat people with genetic conditions and assists in care planning

## Dentist

Manages the health of your teeth and mouth, and may perform procedures to treat complications, like delayed tooth development and insufficient tooth enamel

## Additional specialists you see:

#### **IMPORTANT SAFETY INFORMATION (cont)**

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

- 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:

 $\circ\;$  Your health care provider will check to see if you are pregnant before you start treatment with <code>VIJOICE</code>



# Important Safety Information (cont)

#### Females who can become pregnant:

- 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.

**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.

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 <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.



# Need help getting started?

Learn more about potential financial assistance and other resources at <u>VIJOICE.com</u>.





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