VPRIV®
velaglucerase alfa
for injection

A GUIDE FOR PATIENTS & CAREGIVERS

WITH YOU ALL THE WAY

Whether you're considering treatment for yourself or for a loved one, choosing the right therapy is a vital part of any patient's experience. This brochure can help you decide if you should talk to your doctor about using VPRIV for your treatment journey.

INDICATION

VPRIV® (velaglucerase alfa) for injection is a prescription medication indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.

IMPORTANT SAFETY INFORMATION

Hypersensitivity reactions, including serious allergic reactions (anaphylaxis) have occurred. VPRIV should be administered under the supervision of a healthcare professional. VPRIV is given every other week by intravenous infusion that typically takes up to 60 minutes. Appropriate medical support should be available when VPRIV is administered. The most serious side effects in patients treated with VPRIV were hypersensitivity reactions.

Please see Important Safety Information on page 22 and **click here** for Full Prescribing Information.

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> *"Sharing my story with others, I think, will help people understand a bit more about what the condition is. And to hear it from a patient can make it more real and help you understand it a lot better."*

Katie
Living with Type 1 Gaucher

This image is for illustrative purposes only, and does not depict an actual patient.

CONTENTS

This brochure has been developed to help you learn more about type 1 Gaucher disease and treatment with VPRIV.

This guide should not replace the advice of your healthcare provider. Remember to **always speak with your doctor first** if you have any questions about type 1 Gaucher disease and to determine if VPRIV is right for you.

Please see the **glossary** on our website for a list of commonly used terms found in this brochure.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Hypersensitivity reactions were the most commonly observed side effects in patients treated with VPRIV in clinical studies. The most commonly observed symptoms of hypersensitivity reactions were: headache, dizziness, low blood pressure, high blood pressure, nausea, tiredness/weakness, and fever. Hypersensitivity reactions in the clinical trials include any event considered related to and occurring within up to 24 hours of VPRIV infusion, including one case of anaphylaxis. Generally the reactions were mild and, in patients not previously treated, occurred mostly during the first 6 months of treatment and tended to occur less frequently with time. After the drug was approved, additional hypersensitivity reactions of chest discomfort, difficulty breathing, itching and vomiting have been reported. In some cases, vomiting can be serious and require hospitalization and/or stopping the medication.

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WHAT IS GD1?

Type 1 Gaucher (go-SHAY) disease (GD1) is a rare, genetic condition. As a genetic disease, GD1 typically runs in families. People with this condition either have too little or do not have enough activity of an enzyme called glucocerebrosidase (GLOO-ko-SER-e-bro-si-daze). This enzyme breaks down a fatty substance called glucocerebroside (GLOO-ko-SER-e-bro-side). When the enzyme does not work properly, the fatty substance builds up in cells and causes those cells to enlarge. This may affect different organs throughout the body over time, which is why GD1 is considered to be a progressive condition.

HOW COMMON IS GD1?

Type 1 Gaucher disease is considered rare, as it only affects ~1–9 in 100,000 people within the overall population. However, because it is an inherited, genetic condition, it can be more prevalent in certain communities, such as those of Ashkenazi Jewish descent.

~1–9 IN 100,00 PEOPLE WITHIN THE OVERALL POPULATION HAVE TYPE 1 GAUCHER DISEASE

~1 IN 600 WITHIN THE ASHKENAZI JEWISH COMMUNITY HAVE TYPE 1 GAUCHER DISEASE

~1 IN 17 WITHIN THE ASHKENAZI JEWISH COMMUNITY ARE CARRIERS OF THE DISEASE

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HOW IS GD1 INHERITED?

Type 1 Gaucher disease is a hereditary condition, which means it can be passed along through families by their genes. Two copies of a faulty gene are required for an individual to be affected, one copy from each parent. If somebody has one gene, they do not typically have Type 1 Gaucher disease, but are known as a 'carrier,' and they may pass on the faulty gene.

It is possible to be a carrier even if you are not affected by symptoms of the condition yourself. If you are concerned, talk to your doctor about genetic screening. It may be worthwhile encouraging other members of your family to consider genetic screening as well, especially if you are a member of a community with a higher prevalence of GD1.

IF BOTH PARENTS ARE CARRIERS

50%
CHANCE A CHILD WILL BE A CARRIER

25%
CHANCE A CHILD WILL HAVE GAUCHER

25%
CHANCE A CHILD WILL BE UNAFFECTED

If you are of Ashkenazi Jewish descent, genetic screening is recommended for you and your family members. Please **speak to your doctor** for more information and **visit our website** to learn more.

Please see additional Important Safety Information on page 22 and **click here** for Full Prescribing Information.

TYPE 1 GAUCHER DISEASE

SIGNS AND SYMPTOMS

Type 1 Gaucher disease impacts each individual differently, so signs and symptoms may present in different ways for different people. It can also be tricky to diagnose because different symptoms may present at different ages for different individuals, can fluctuate with disease progression, and may mimic the symptoms of other diseases. Below are some of the more common signs of GD1 and the presenting symptoms that may link to underlying causes:

- **Low red blood cell count – tiredness and weakness**
- **Enlarged spleen and/or liver – stomach discomfort and pain**
- **Low platelet (blood-clotting cell) count – bruising and bleeding**

Please remember, not all symptoms of GD1 are easily noticeable or interpretable; that's why it's important to talk to your doctor and have your condition consistently monitored, to ensure the most effective management of your symptoms. If you are concerned about any of these signs and symptoms or suspect type 1 Gaucher disease, ask your doctor, who will be able to carry out the relevant tests.

COMMON SIGNS AND SYMPTOMS OF TYPE 1 GAUCHER DISEASE

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CONSIDER VPRIV

VPRIV is indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease and has established safety and efficacy data in patients aged 4 years and older, who were in various stages of life. Whether you're considering treatment for yourself or for a loved one, choosing the right one is a vital part of any patient's experience with type 1 Gaucher disease. To help understand if VPRIV is the right choice for you or a loved one, consider the following:

10+ YEARS' EXPERIENCE

VPRIV has over 10 years of real-world experience. VPRIV was first approved by the FDA in 2010 and has been indicated for long-term use to treat patients with type 1 Gaucher disease ever since.

LARGEST CLINICAL TRIAL FOR ERT

VPRIV was studied in the largest clinical trial program of an ERT for type 1 Gaucher disease; up to 99 patients in various life stages (aged 4 years and older) were evaluated across three clinical trials and a long-term extension study.

DERIVED FROM HUMAN CELLS

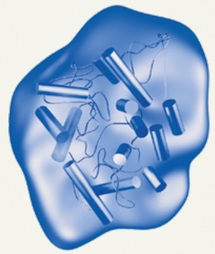
VPRIV is an ERT, specifically designed to match and replace the natural human enzyme (glucocerebrosidase) that is missing with type 1 Gaucher disease. VPRIV is an ERT for GD1 that is made from a human cell line; this design is intended to facilitate targeted uptake of VPRIV into cells.

60-MINUTE INFUSIONS

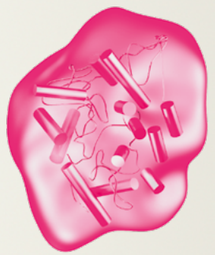
For patients 4 years and older who are new to treatment, VPRIV is administered as a 60-minute infusion, taken once every other week under the supervision of a healthcare professional.

HOW IS VPRIV MADE?

VPRIV is an ERT for treatment of GD1 made from a human cell line. It has the same amino acid sequence as the naturally occurring human enzyme, glucocerebrosidase, that is found in the body. It is designed to facilitate targeted uptake of VPRIV into cells.



GLUCOCEREBROSIDASE



VPRIV

IMPORTANT SAFETY INFORMATION (CONTINUED)

If anaphylactic or other acute reactions occur, your healthcare provider will immediately discontinue the infusion of VPRIV and initiate the appropriate medical treatment. A hypersensitivity reaction should be treated based on the severity of the reaction. Your healthcare provider may manage a reaction by slowing the infusion rate or treating with medicine such as antihistamines, fever-reducing agents and/or corticosteroids or possibly stopping the medication and then restarting with a longer infusion time. For patients who have had symptoms of hypersensitivity reaction to enzyme replacement therapy, the doctor may consider treating the patient with antihistamines and/or corticosteroids before an infusion to help prevent such a reaction from happening.

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.

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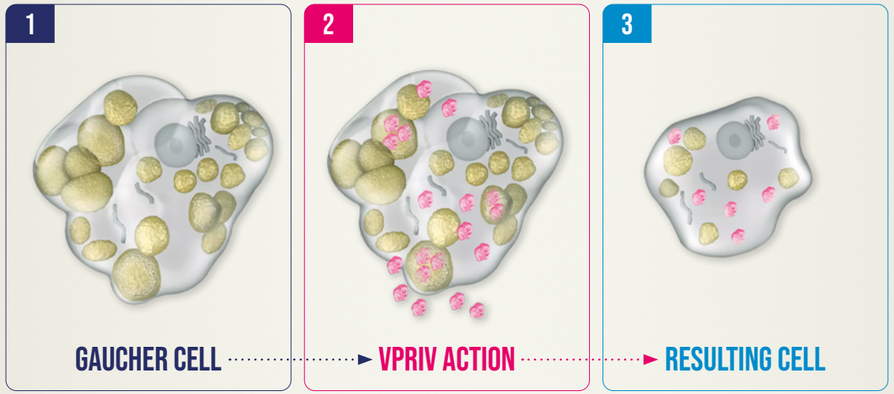
HOW DOES VPRIV WORK?

VPRIV is specifically designed to match and replace the enzyme, glucocerebrosidase, which is deficient in those with type 1 Gaucher disease, and to replicate its job: to remove excess glucocerebroside, a fatty substance that builds up in cells and causes them to enlarge.



Gaucher cells are swollen due to the accumulation of a fatty substance known as glucocerebroside.

VPRIV is absorbed into the cell. Once inside the cell, VPRIV breaks down glucocerebroside.

Like the naturally occurring human enzyme, VPRIV breaks down glucocerebroside, reducing the overall amount in the cell.

For illustration purposes only. In vitro test results do not necessarily correlate with clinical efficacy.

VPRIV may affect individuals differently, and each person's experience with VPRIV will be unique.

IMPORTANT SAFETY INFORMATION (CONTINUED)

The most commonly reported side effects during clinical studies (in ≥10% of patients) were hypersensitivity reactions, headache, dizziness, abdominal pain, nausea, back pain, joint pain, increased time it takes for blood to clot, tiredness/weakness, and fever.
In clinical studies, the overall frequency of side effects was generally higher in the patients not previously treated with ERT than in the patients who switched from imiglucerase to VPRIV.

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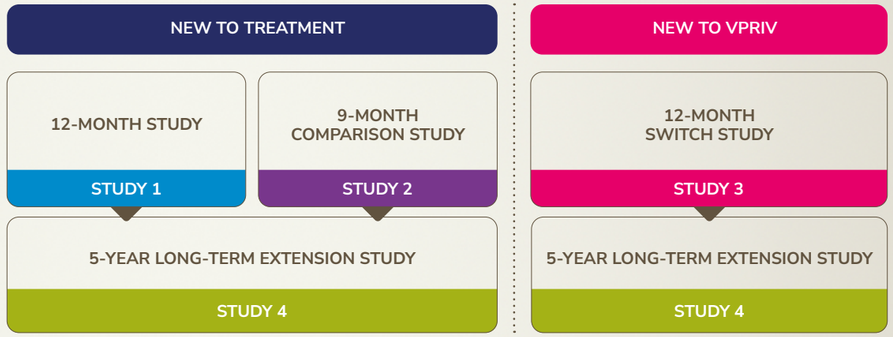
VPRIV CLINICAL STUDIES

VPRIV was studied in the largest clinical trial program for an ERT for type 1 Gaucher disease.

During these trials, the safety and efficacy of VPRIV were evaluated in 99 adults and children aged 4 years and older who had been diagnosed with GD1, in various stages of life, across three initial clinical trials. Some of these patients then went on to take part in a 5-year long-term extension study.

VPRIV CLINICAL TRIAL OVERVIEW



New to treatment (treatment-naïve): studies involving patients who were not receiving treatment for type 1 Gaucher disease prior to enrollment in the clinical trial.

New to VPRIV (treatment-experienced): studies involving patients who were receiving imiglucerase treatment for at least 2.5 years before starting treatment with VPRIV as part of the clinical trial.

Patients who completed Studies 1, 2, or 3 could participate in Study 4. In all studies, VPRIV was administered intravenously over 60 minutes at a maximum dose of 60 Units/kg once every other week.

Visit **www.vpriv.com** to learn more about our clinical trials.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Talk to your doctor if you are pregnant, plan to be pregnant, are breastfeeding, or plan to breastfeed.

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VPRIV SAFETY AND TOLERABILITY

The most serious and most commonly observed side effects for patients treated with VPRIV in clinical studies were hypersensitivity reactions, which included: headache, dizziness, low blood pressure, high blood pressure, nausea, tiredness/weakness, and fever. The most common adverse reactions, observed in ≥10% of the 94 patients (adults and children aged 4 and older), were:

SIDE EFFECT	NEW TO TREATMENT n=54 n (%)	SWITCHING TO VPRIV n=40 n (%)
Allergic reaction†	28 (52)	9 (23)
Headache	19 (35)	12 (30)
Dizziness	12 (22)	3 (8)
Fever	12 (22)	5 (13)
Stomach pain	10 (19)	6 (15)
Back pain	9 (17)	7 (18)
Joint pain (knee)	8 (15)	3 (8)
Tiredness/weakness	8 (15)	5 (13)
Increased time it takes for blood to clot	6 (11)	2 (5)
Nausea	3 (6)	4 (10)

† Denotes any event considered related to and occurring within up to 24 hours of VPRIV infusion, including one case of anaphylaxis.

- Across five clinical studies, including initial phase 1 and 2 clinical trials, the safety profile of VPRIV was similar between children (aged 4–17 years) and adult patients
- The safety of VPRIV has not been established in children younger than 4 years of age
- Rash, increased time it takes for blood to clot, and fever were more commonly seen in children than in adults
- Older patients (≥65 years old) had a similar side effect profile to that of children and adult patients
- In general, doses for older patients should be selected cautiously by their doctor, taking into consideration any other existing or potential medical conditions

Please speak to your doctor to discuss any questions you may have about treatment with VPRIV.

IMPORTANT SAFETY INFORMATION (CONTINUED)

The safety and efficacy profiles were similar in pediatric (ages 4 to 17) and adult patients. The safety of VPRIV has not been established in patients under 4 years of age. Side effects more commonly seen in pediatric patients compared to adult patients include (>10% difference): rash, increased time it takes for blood to clot, and fever.

TALK TO YOUR DOCTOR ABOUT VPRIV

Your doctor will be your main point of contact for any questions or concerns, but you are likely to see a variety of other specialists to help manage your symptoms and treatment. Your multidisciplinary management team may include the following specialists:

TYPE OF SPECIALIST	WHAT DO THEY DO?
Dietician	A healthcare professional who can treat specific health conditions by providing recommendations to do with your diet, eating habits, and other areas associated with nutrition.
Genetic counselor	A professional who can guide and support patients seeking more information about how inherited diseases and conditions might affect them and how to interpret test results.
Geneticist	A doctor who provides comprehensive diagnostic, management, and genetic counseling services for patients with genetic disorders.
Hematologist	A doctor who specializes in diagnosis and treatment of disorders associated with the blood, bone marrow, and lymphatic system.
Hepatologist	A doctor who specializes in the diagnosis and treatment of problems associated with the liver, gallbladder, bile ducts, and pancreas.
Internist	A medical doctor who specializes in the internal organs and systems of the body.
Neurologist	A doctor who specializes in the diagnosis and treatment of problems associated with the brain and nervous system.
Oncologist	A doctor who specializes in the diagnosis and treatment of cancer throughout the course of the disease.
Orthopedist	A specialist who uses surgical and non-surgical approaches to treat disorders or injuries of the bones, joints, or related muscles.
Pain-management specialist	A medical doctor with special training in the evaluation and management of pain.
Physical therapist	A healthcare specialist who evaluates and helps to manage illnesses or injuries using techniques such as exercises, stretching, use of equipment, and other hands-on techniques.
Mental health therapist	A mental health therapist, or counselor, is a trained professional who engages in conversations with patients and their families to address emotional and personal concerns. Their role includes assisting individuals in making informed decisions related to their mental health.

IMPORTANT SAFETY INFORMATION (CONTINUED)

The side effect profile in elderly patients was generally similar to that seen in pediatric and other adult patients. In general, dose selection for an elderly patient should be approached cautiously, considering other existing medical conditions.

Please see additional Important Safety Information on page 22 and **click here** for Full Prescribing Information.

VPRIV® velaglucerase alfa for injection

HOW TO TAKE VPRIV

VPRIV is a **60-minute** infusion administered once every other week at an infusion center, which is a site of care that focusses specifically on medicines delivered intravenously, under the supervision of a trained healthcare professional.

VPRIV is an infusion, which means that it is administered intravenously, or directly into the bloodstream.

Your infusion will be scheduled for 60 minutes, although you may need to factor in some additional time for pre-infusion preparation and post-infusion monitoring.

Your doctor will adjust and decide the best dose for you based on your therapy goals and body weight. The recommended starting dose for new patients 4 years of age and older is 60 Units/kg.

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HOW TO TAKE VPRIV

If you tolerate VPRIV infusions well, you may eventually be able to work with your doctor to arrange for your infusions to be taken at home. In these cases, a healthcare professional would come to your home to administer the VPRIV infusions for you. Talk to your doctor if this is something that you are interested in.

Speak to your doctor to see if home infusions are an option for you in your treatment journey.

IMPORTANT SAFETY INFORMATION (CONTINUED)

As with all therapeutic proteins, there is a potential for developing antibodies to VPRIV. In clinical studies, 1 of 54 (2%) patients who had not previously been treated with ERT, who were then treated with VPRIV, developed antibodies. One additional patient developed antibodies to VPRIV during an extension study. It is unknown if having antibodies to VPRIV is associated with a higher risk of infusion reactions. Patients with an immune response to other enzyme replacement therapies who are switching to VPRIV should continue to be monitored for antibodies to VPRIV.

SUPPORT PROGRAMS

OnePath

When you're prescribed VPRIV® (velaglucerase alfa), OnePath dedicated product support is here for you. OnePath® is a no-cost program offered by Takeda that provides personalized product support to eligible, enrolled patients and their caregivers. From your first treatment conversation, and throughout your journey, our goal is to make your experience a little easier.

There may be a few different members that make up your dedicated support team, but your Patient Support Manager (PSM) will be your primary point of contact. Your PSM will work with you one-on-one to help with many aspects of your treatment with VPRIV, including:

- **Financial Assistance Options**
  Copay assistance , if you qualify*, as well as assistance with navigating insurance coverage
- **Resources and Education**
  Direct you to community support resources and advocacy organizations, and help you get access to OnePath's free mobile app
- **Assistance During Life Transitions**
  Connect you with resources to help you manage your treatment when things change, including if you are moving, going to college, or changing jobs

* To be eligible, you must be enrolled in OnePath and have commercial insurance. Other terms and conditions apply. Call OnePath for more details.

If you have any questions or need assistance, do not hesitate to reach out. We're available on 1-866-888-0660 from Monday to Friday between 8.30 AM and 8.00 PM ET or visit us at **www.vpriv.com/patient-support/onepath-product-support** anytime.

Fill in a OnePath® Start Form with your doctor and visit **OnePath.com** to learn more.

Joyce and Laura
Patient Support Managers

RESOURCES & SUPPORT

SUPPORT PROGRAMS

QuickStart

QuickStart can help streamline starting treatment with VPRIV.

When starting VPRIV – whether you're new to ERT or just switching from another treatment – there may be some administrative hurdles with insurance. One of the most commonly encountered issues that has the potential to delay the start of your treatment is called a prior authorization (PA).

A PA is when your insurance company requires your doctor to fill out additional paperwork before your prescription is processed. This can delay you from starting treatment while your paperwork is being evaluated and processed.

QuickStart allows eligible patients to receive their infusion while the PA is still being reviewed. You could receive up to two free doses of VPRIV if you are eligible and it is prescribed by your doctor.

Fill in a QuickStart Form with your doctor and visit **OnePath.com** to learn more.

PreppedAhead™

PreppedAhead™ expedites infusion preparation to save you time.

What many patients don't always expect when starting an ERT is that in addition to infusion time, there is usually extra time needed for the site of care to prepare the infusion.

PreppedAhead™ is a program that provides you with the option of having your site of care prepare your treatment before you arrive — so you don't have to wait as long before your infusion begins.

This service is only available to patients enrolled in OnePath® at sites of care that are enrolled in the PreppedAhead™ program.

Talk to your Patient Support Manager about PreppedAhead™ today, and visit **OnePath.com** to learn more.

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ADDITIONAL RESOURCES

Wherever your GD1 treatment journey takes you, we will be with you all the way. Below you can find some further resources for more information, as well as places to find support from the type 1 Gaucher disease community:

GAUCHER COMMUNITY ALLIANCE (GCA)
The GCA provides emotional support, information, and patient and family resources for anyone affected by Gaucher disease:
www.gauchercommunity.org

NATIONAL ORGANIZATION FOR RARE DISORDERS (NORD)
Discover the advocacy, research, education, and patient services provided by NORD to patients with rare diseases throughout the US:
www.rarediseases.org

NATIONAL GAUCHER FOUNDATION (NGF)
Find out more about the financial, educational, and research programs carried out by the NGF to support the Gaucher community:
www.gaucherdisease.org

JEWISH GENETIC DISEASE CONSORTIUM
A group dedicated to preventing Jewish genetic diseases through awareness:
www.jewishgeneticdiseases.org

NATIONAL SOCIETY OF GENETIC COUNSELORS
An organization that helps people find genetic counselors (a type of healthcare professional who can help guide and support patients with inherited diseases and conditions) in their area:
www.nsgc.org

ADDITIONAL RESOURCES

If you're interested in learning more about VPRIV, there are more resources available online.

VPRIV EMAILS
Stay up to date with the latest VPRIV news and updates by signing up to receive occasional emails from us:
www.vpriv.com/stayupdated/opt-in

VPRIV WEBSITE
Visit for more information about VPRIV, including the largest clinical trial program for GD1, available support programs, FAQs, and further resources:
www.vpriv.com

"You're going to be OK. You're going to be brave and do something new. You can do it."

Emily & Susan, Emily's Mom
Living with Type 1 Gaucher

IMPORTANT SAFETY INFORMATION (CONTINUED)

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NOTES

> *My piece of advice is just, don't let it define you. There's going to be things that you have to change, but at the end of the day, you're still you.*

Aaron
Living with Type 1 Gaucher

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To learn more about how VPRIV is made and how it works, visit www.vpriv.com. Talk to your healthcare professional to see if VPRIV could be the right choice for you.

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