VPRIV®
velaglucerase alfa
for injection

VPRIV DOSING & INFUSION GUIDE

This guide contains full preparation and administration information for healthcare professionals administering VPRIV.

You understand your patients and the various stages they'll experience in their individual journeys. We understand your needs in supporting your patients on their journey.

Our goal is to help make sure you're not just ready, you're VPRIV Ready.

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
Initiate VPRIV in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment.
If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue VPRIV and immediately initiate appropriate medical treatment, including use of epinephrine.
Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

Please see additional Important Safety Information throughout and on pages 14–15. Please click here for Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

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ABOUT VPRIV

- Type 1 Gaucher disease (GD1) is a rare, autosomal recessive, chronic, progressive disorder caused by deficient activity of the lysosomal enzyme glucocerebrosidase[1–3]
- VPRIV is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for first-line enzyme replacement therapy (ERT) for GD1.[4] VPRIV is specifically designed to match and replace the natural human enzyme[4,5]
- VPRIV is administered as a **60-minute intravenous (IV) infusion** once every other week under the supervision of a healthcare professional[4]
- VPRIV is dosed according to body weight[4]
- Always refer to the **Prescribing Information** before administering VPRIV

STORAGE & HANDLING

- VPRIV is a sterile, white to off-white, lyophilized powder supplied in individually packaged single-dose glass vials, requiring reconstitution and dilution prior to use[4]
- VPRIV should be stored refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton away from light. Do not freeze VPRIV[4]
- Check the expiration date on the vial and DO NOT use VPRIV after the expiration date[4]

IMPORTANT SAFETY INFORMATION (CONTINUED)

Life-threatening hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with enzyme replacement therapies, including VPRIV. VPRIV-treated patients have had these reactions occur in clinical studies and postmarketing experience.

Hypersensitivity reactions were the most commonly observed adverse reactions in patients treated with VPRIV in clinical studies. Patients were not routinely pre-medicated prior to infusion of VPRIV. The most commonly observed symptoms of hypersensitivity reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia. 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 treatment-naïve patients, onset occurred mostly during the first 6 months of treatment and tended to occur less frequently with time. Additional hypersensitivity reactions of chest discomfort, dyspnea, pruritus and vomiting have been reported in post-marketing experience. In some cases vomiting can be serious, requiring hospitalization and/or drug discontinuation.

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VPRIV DOSING

- VPRIV is administered as a 60-minute IV infusion once every other week under the supervision of a healthcare professional[4]
- Always refer to VPRIV's **Prescribing Information**, which contains complete dosing and administration information, before administering VPRIV

TREATMENT-NAÏVE PATIENTS	60 MINUTE INFUSION	TREATMENT-EXPERIENCED PATIENTS
The recommended starting dosage in treatment-naïve patients (adults and children, aged 4 years and older) is 60 U/kg administered once every other week.[4,6]		Patients (adults and children, aged 4 years and older) currently being treated on a stable dosage of imiglucerase for type 1 Gaucher disease may be switched to VPRIV by starting treatment with VPRIV at the previous imiglucerase dosage 2 weeks after the last imiglucerase dose.[4,7]

- Dose adjustments may be made on an individual basis based on the achievement and maintenance of therapeutic goals[4]
- VPRIV is dosed according to body weight[4]

IMPORTANT SAFETY INFORMATION (CONTINUED)

Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Administration of VPRIV should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis. Initiate VPRIV in a healthcare setting with appropriate medical monitoring and support measures including access to cardiopulmonary resuscitation equipment.

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VPRIV DOSING CALCULATION

Precise dosing requires a patient's exact weight and an individual calculation by the healthcare professional. **Always use the exact unit of the required VPRIV dosage and dispose of unused product.**[4]

CALCULATION STEPS	EXAMPLE CALCULATION
1 Obtain patient's weight[4]	Patient's weight = 21 kg
2 Recommended dose of VPRIV is 60 U/kg patient body weight administered once every other week as an IV infusion[4] **Calculate the dosage of VPRIV required*:** Patient weight (kg) × 60 U/kg	21 kg × 60 U/kg of VPRIV = 1,260 U
3 VPRIV is supplied in 400-U single-dose vials[4] **Calculate the number of vials needed†:** Required VPRIV dosage ÷ 400	1,260 ÷ 400 = 3.15 vials needed (4 vials are needed to extract 1,260 units of VPRIV)

**Recommended dose of VPRIV is 60 U/kg patient body weight administered once every other week as an intravenous (IV) infusion.[4] This will change if lbs is used in the calculation instead.*
†1 vial of VPRIV = 400 Units (U).[4]

Click here to use the VPRIV Dosing Calculator.

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WEIGHT-BASED DOSING REFERENCE

VPRIV is dosed according to body weight.[4] It is important to assess the patient's current condition, including weight, before each infusion.

CALCULATION:	Number of U/kg prescribed × patient's weight (kg) / 400 =		Number of 400-U vials needed
Weight in lbs	**Weight in kg**	**Recommended Units (60 U/kg × kg)**	**400-U Vials Needed**
40	18.1	1,089	2.7
45	20.4	1,225	3.1
50	22.7	1,361	3.4
55	24.9	1,497	3.7
60	27.2	1,633	4.1
65	29.5	1,769	4.4
70	31.8	1,905	4.8
75	34.0	2,041	5.1
80	36.3	2,177	5.4
85	38.6	2,313	5.8
90	40.8	2,449	6.1
95	43.1	2,585	6.5
100	45.4	2,722	6.8
105	47.6	2,858	7.1
110	49.9	2,994	7.5
115	52.2	3,130	7.8
120	54.4	3,266	8.2
125	56.7	3,402	8.5
130	59.0	3,538	8.8
135	61.2	3,674	9.2
140	63.5	3,810	9.5
145	65.8	3,946	9.9
150	68.0	4,082	10.2
155	70.3	4,218	10.5
160	72.6	4,354	10.9
165	74.8	4,491	11.2
170	77.1	4,627	11.6
175	79.4	4,763	11.9
180	81.6	4,899	12.2
185	83.9	5,035	12.6
190	86.2	5,171	12.9
195	88.5	5,307	13.3
200	90.7	5,443	13.6
205	93.0	5,579	13.9
210	95.3	5,715	14.3
215	97.5	5,851	14.6
220	99.8	5,987	15.0
225	102.1	6,123	15.3
230	104.3	6,260	15.6
235	106.6	6,396	16.0
240	108.9	6,532	16.3
245	111.1	6,668	16.7
250	113.4	6,804	17.0

These are example body weights only. Precise dosing requires patient's exact weight and an individual calculation by the healthcare professional.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Management of hypersensitivity reactions should be based on severity of the reaction, such as slowing the infusion rate, treatment with medications such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with increased infusion time. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue VPRIV and immediately initiate appropriate medical treatment, including use of epinephrine. In cases where patients have exhibited symptoms of hypersensitivity to velaglucerase alfa or excipients in the drug product or to other enzyme replacement therapy, pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

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SETTING UP FOR A VPRIV INFUSION

PATIENT ASSESSMENT

As with any infusion or medical procedure, it is important to assess your patient's current condition and review their medical history, including any prior ERT for GD1.[4]

Initiate VPRIV treatment in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment.[4]

Administration of VPRIV should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis.[4]

1. Obtain the patient's weight.[4]
2. Check preinfusion vital signs and labs, if required per facility infusion protocol.
3. Review previous infusion notes, if any, to determine if the patient has had infusion reactions to an ERT and to assess any changes since the last visit.[4]
4. Consider pre-treatment with antihistamines and/or corticosteroids in patients who exhibited symptoms of hypersensitivity associated with prior velaglucerase alfa product infusions.[4]
5. Notify the patient's treating physician if the infusion cannot be administered.[4]

IMPORTANT SAFETY INFORMATION (CONTINUED)

The most common adverse reactions during clinical studies (in ≥10% of patients) were hypersensitivity reactions, headache, dizziness, abdominal pain, nausea, back pain, joint pain, prolonged activated partial thromboplastin time (aPTT), fatigue/asthenia, and pyrexia. In clinical studies, the overall frequency of adverse events was generally higher in the population naïve to enzyme replacement therapy (ERT) than in the population switched from imiglucerase to VPRIV.

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SUPPLIES NEEDED

VPRIV is a lyophilized powder that requires reconstitution and dilution, using sterile technique, prior to IV infusion.[4]

The following supplies will help with the preparation and administration of VPRIV:

IV Apparatus

- IV infusion pump
- IV infusion tubing
- IV start kit
- In-line low protein-binding 0.2 or 0.22 µm filter

Equipment

- Syringes and ≤20 gauge needle
- Angiocatheter
- Anaphylaxis kit
- Antihistamines and/or corticosteroids as pre-treatment as needed or per facility infusion protocol
- If initiating treatment, appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment, should be available

Solutions

- Sterile Water for Injection, USP
- 100 mL of 0.9% Sodium Chloride Injection, USP

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VPRIV PREPARATION & ADMINISTRATION

RECONSTITUTION AND DILUTION

VPRIV is a lyophilized powder that requires reconstitution and dilution, using sterile technique, prior to IV infusion.[4] VPRIV should be prepared as follows[4]:

1. Determine the number of vials to be reconstituted based on the individual patient's weight and the prescribed dose. See Dosing Calculation on page 5 for VPRIV dosing guidelines. Remove the required number of vials from the fridge. Do not use VPRIV after the expiration date.

2. Inject 4.3 mL of Sterile Water for Injection, USP, into a vial containing VPRIV powder. Mix gently, **do not shake**. The reconstituted VPRIV solution will have a 100 U/mL concentration (400 U of VPRIV in 4 mL of solution). If more vials are needed, repeat the above steps.

3. Visually inspect the solution in the vials. It should be clear to slightly opalescent and colorless. **Do not use if the solution is discolored or if foreign particulate matter is present.***

4. Use a single syringe to withdraw the calculated dosage of drug from the appropriate number of prepared vials. See Dosing Calculation on page 5 for VPRIV dosing guidelines. Using a separate syringe, withdraw air from a bag of 100 mL of 0.9% Sodium Chloride Injection suitable for IV administration. Inject the calculated dosage of prepared VPRIV directly into the 0.9% Sodium Chloride Injection to dilute.

5. Mix gently, **do not shake**. Slight flocculation (white irregularly shaped particles) may occasionally occur. A diluted solution with slight flocculation is acceptable for administration.

6. Place medication label on the IV bag according to site/organization policy. Use immediately. If immediate use is not possible, the diluted VPRIV solution may be stored for up to 24 hours at 36°F to 46°F (2°C to 8°C). Do not freeze, and protect from light. Complete the infusion within 24 hours of reconstitution.

*Contact Medical Information at 1-866-888-0660, option 2 or email medinfous@takeda.com for all US inquiries if the solution is discolored or if foreign particulate matter is present.

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VPRIV ADMINISTRATION

- VPRIV should be administered under the supervision of a healthcare professional[4]
- Diluted VPRIV should be administered through an in-line, low protein-binding 0.2 or 0.22 µm filter. VPRIV should not be infused with other products in the same infusion tubing. The compatibility of VPRIV in a solution with other products has not been evaluated[4]

1. Attach IV tubing to the bag of VPRIV solution. IV tubing should have an in-line filter in place.[4]

2. Use normal saline to prime tubing and expel all air.

3. Set the infusion to administer at the rate prescribed. A 60-minute infusion is recommended.[4]

4. Select the IV infusion site; this will vary by patient and may include: antecubital, wrist, or hand veins, or a central venous catheter. Follow your facility's policies for IV insertion, medication infusion, and disposal of biohazardous waste.

5. Begin VPRIV therapy infusion with the flow-regulating device or IV pump. Monitor the patient regularly. If anaphylactic or other acute reactions occur, discontinue VPRIV immediately and immediately initiate appropriate medical treatment, including use of epinephrine.[4]

Please click here to see Boxed Warning for hypersensitivity reactions, including anaphylaxis, and Section 5.1 of the Warnings and Precautions section of the Prescribing Information for important information on hypersensitivity reactions.

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. Adverse reactions more commonly seen in pediatric patients compared to adult patients include (>10% difference): rash, prolonged aPTT, and pyrexia. The adverse reaction profile in elderly patients was consistent with that previously observed across pediatric and adult patients. In general, dose selection for an elderly patient should be approached cautiously, considering comorbid conditions.

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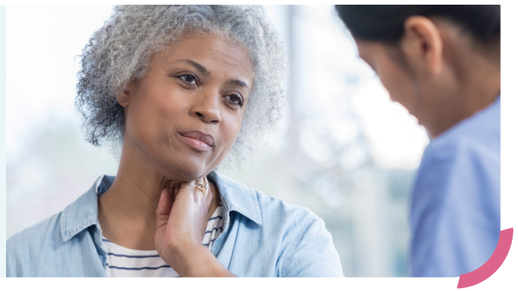
PATIENT SUPPORT PROGRAMS

Takeda Patient Support
Your Source for Education and Access

Support specialists your patient can count on

When you prescribe VPRIV for your patient, Takeda Patient Support is here for them.

Our support specialists can help with your patient's questions and concerns, and provide them with the information they need.



For onboarding, access, and reimbursement assistance, some of our services may include:

- **Benefits investigation** to help determine your patient's insurance benefits and eligibility for certain services
- **Prior authorization (PA), reauthorization, and appeals information** in coordination with your patient's insurance company to determine any requirements
- **Specialty pharmacy** (or site of care) triage and coordination
- **Information about financial assistance options** if they're eligible. In addition, our support specialists can assist with Co-Pay Assistance Program enrollment,* as well as provide information about other programs they may be eligible for

*To be eligible, the patient must be enrolled in Takeda Patient Support, and have commercial insurance. Other terms and conditions apply. Call for more details.

Need assistance?

Our support specialists are never more than a tap or a call away — **1-866-888-0660**, Monday through Friday, 8:30 am to 8:00 pm ET. *If English is not your patient's preferred language, a support specialist can also communicate over the phone in a variety of languages — including Spanish, Yiddish, and more — using a translation service.*

Need to enroll your patient?

Click here to visit our convenient online enrollment portal or click here to download a Start Form to Print & Fax.

To learn more about Takeda Patient Support, click **here**.

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QuickStart

Streamline treatment initiation for eligible patients:

- Some insurance plans may require additional paperwork, called a prior authorization, before treatment can be initiated, which can cause delays
- QuickStart allows eligible patients to receive up to **two free VPRIV infusions** while the prior authorization is still being reviewed
- Additional terms and conditions apply

To be eligible for QuickStart, patients must be enrolled in Takeda Patient Support. When filling in a VPRIV Start Form with your patient, check mark the QuickStart box in Section 6 to enroll your patient in the QuickStart program.

PreppedAhead™

Expedite infusion preparation with PreppedAhead so your patient can save time before their infusions:

- VPRIV is a 60-minute infusion, administered once every other week.[4] PreppedAhead provides patients with the option of having their site of care prepare treatment before they arrive to save time
- PreppedAhead is only available to eligible patients enrolled in Takeda Patient Support, and whose site of care is enrolled in the PreppedAhead program

Click here to download and fill in a PreppedAhead Sign-up Form.

IMPORTANT SAFETY INFORMATION (CONTINUED)

As with all therapeutic proteins, there is a potential for immunogenicity. In clinical studies, 1 of 54 (2%) enzyme treatment-naïve patients treated with VPRIV developed IgG class antibodies (neutralizing in an *in vitro* assay). One additional patient developed IgG antibodies to VPRIV during an extension study. It is unknown if the presence of IgG antibodies to VPRIV is associated with a higher risk of infusion reactions. Patients with an immune response to other ERTs who are switching to VPRIV should continue to be monitored for antibodies to VPRIV.

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Initiate VPRIV in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment.
If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue VPRIV and immediately initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

Life-threatening hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with enzyme replacement therapies, including VPRIV. VPRIV-treated patients have had these reactions occur in clinical studies and postmarketing experience.

Hypersensitivity reactions were the most commonly observed adverse reactions in patients treated with VPRIV in clinical studies. Patients were not routinely pre-medicated prior to infusion of VPRIV. The most commonly observed symptoms of hypersensitivity reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia. 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 treatment-naïve patients, onset occurred mostly during the first 6 months of treatment and tended to occur less frequently with time. Additional hypersensitivity reactions of chest discomfort, dyspnea, pruritus and vomiting have been reported in post-marketing experience. In some cases vomiting can be serious, requiring hospitalization and/or drug discontinuation.

Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Administration of VPRIV should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis. Initiate VPRIV in a healthcare setting with appropriate medical monitoring and support measures including access to cardiopulmonary resuscitation equipment.

Management of hypersensitivity reactions should be based on severity of the reaction, such as slowing the infusion rate, treatment with medications such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with increased infusion time. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue VPRIV and immediately initiate appropriate medical treatment, including use of epinephrine. In cases where patients have exhibited symptoms of hypersensitivity to velaglucerase alfa or excipients in the drug product or to other enzyme replacement therapy, pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

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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. Adverse reactions more commonly seen in pediatric patients compared to adult patients include (>10% difference): rash, prolonged aPTT, and pyrexia. The adverse reaction profile in elderly patients was consistent with that previously observed across pediatric and adult patients. In general, dose selection for an elderly patient should be approached cautiously, considering comorbid conditions.

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Please click here for Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

To report **SUSPECTED ADVERSE REACTIONS**, contact Medical Information at 1-866-888-0660, option 2 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
For assistance with medical inquiries about VPRIV, please contact Takeda at 1-877-TAKEDA-7 (1-877-825-3327) or email medinfous@takeda.com.

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Visit www.hcp.vpriv.com
for more information on VPRIV.

YOU'RE NOT JUST READY,
YOU'RE VPRIV READY

REFERENCES

1. Weinreb NJ, et al. *Semin Hematol*. 2004; 41(4 Suppl 5): 15–22. **2.** Grabowski GA. *Lancet*. 2008; 372(9645): 1263–1271. **3.** Cappellini M-D, et al. *Eur Oncol Haematol*. 2018; 14(1): 50–56. **4.** VPRIV. [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; July 2024. **5.** Brumshtein B, et al. *Glycobiology*. 2010; 20(1): 24–32. **6.** Gonzalez DE, et al. *Am J Hematol*. 2013; 88(3): 166–171. **7.** Zimran A, et al. *Am J Hematol*. 2013; 88(3): 172–178.

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