Takeda Patient Support For VPRIV
Your Source for Education and Access

VPRIV® velaglucerase alfa for injection

VPRIV® (velaglucerase alfa) Patient Start Form

Fax pages 1–3 to **1-888-990-0008** | Phone: **1-866-888-0660**

Please ensure patient reads and signs pages 2 and 3 for appropriate authorizations

1 Prescribing Physician Information

Name (First, Last)

National Provider ID #

Tax ID #

State License #

Street Address

City

State

Zip Code

Telephone

Office Contact

Fax

2 Site of Care Information

Site of Care Name

Street Address

City

State

Zip Code

Telephone

☐ Home Infusion (provide address of Home Infusion Company below)

Office Contact

Fax

National Provider ID #

3 Patient Information

Name (First, Middle Initial, Last)

Age

Last 4 digits of SSN

☐ Male ☐ Female

DOB (Month/Day/Year)

Mobile Telephone

Work Telephone

Home Telephone

Street Address

City

State

Zip Code

Email Address

Patient Weight (kg)

Caregiver Name (First, Last)

Caregiver Telephone

Relationship to Patient

4 Insurance Information

Please attach copies of both sides of patient's insurance card(s)

☐ **Check if patient does not have insurance**

Primary Insurance

Insurance Telephone

Policy Holder Name (First, Last)

Relationship to Patient

Policy ID #

Group #

Pharmacy Plan Name

Rx Bin #

Pharmacy Plan Telephone

Rx PCN #

Secondary Insurance

Insurance Telephone

Policy ID #

Group #

Policy Holder Name (First, Last)

Relationship to Patient

5 Physician Authorization

By signing this form, I certify that therapy with VPRIV is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current VPRIV Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to VPRIV therapy to Takeda Pharmaceutical Company Limited, including its agents or contractors, for the purpose of seeking information related to coverage and/or assisting in initiating or continuing VPRIV therapy. I authorize Takeda Patient Support to transmit this prescription to the appropriate pharmacy designated by me, Patient, or Patient's plan. I agree that product provided through the Program shall only be used for Patient, must not be resold, offered for sale or trade, or returned for credit.

Prescriber Signature (Required) Stamps not acceptable

Date

DISPENSE AS WRITTEN

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Patient Name

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6 Enroll in QuickStart (Optional)

The QuickStart Program provides VPRIV® product at no charge for eligible patients who have been prescribed VPRIV® by a physician while a prior authorization is being reviewed. QuickStart does not cover dosing and administration costs. QuickStart is valid for up to two (2) doses only for each patient. Not valid for prescriptions covered by or submitted for reimbursement under Medicaid, Medicare, or similar state or federal programs.

☐ **Enroll in QuickStart**

7 Patient Authorization to Share Protected Health Information

Patient Name (First, Middle Initial, Last)

DOB (MM/DD/YYYY)

By signing the Patient Authorization section on the second page of this Takeda Patient Support Enrollment Form, I authorize any health plan, physician, health care professional, hospital, clinic, pharmacy provider or other health care provider (collectively, "Providers") to disclose my protected health information, including personal information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Takeda Pharmaceutical Company Limited, its affiliates and their representatives, agents, and contractors (collectively, the "Company" or "Takeda") in connection with the Company's provision of products, supplies, or services. I understand the Company will provide this Information to a specialty pharmacy to fulfill the prescription. This Information may also be used for internal uses by the Company, including data analysis. Further, I understand that my physician, health insurance, and pharmacy providers may receive financial remuneration from the Companies for providing Protected Health Information, which may be used for marketing purposes.

Further, the Company may use this Information for Takeda Patient Support Services ("Services") (if I agree below) such as verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance.

I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may no longer be protected by federal privacy law, including HIPAA. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization at any time by sending written notice of revocation to Takeda Patient Support, 500 Kendall Street, Cambridge, MA 02142. I understand that such revocation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law.

I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to receive Services from Takeda.

Signature of Patient (Required) Date

***Legal Representative Signature** Date

*Legal Representative Name

*Relationship to Patient

*Required only if applicable.

Takeda Patient Support
For VPRIV
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Patient Name

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7 Takeda Patient Support Enrollment

Patient Name (First, Middle Initial, Last)

DOB (MM/DD/YYYY)

REQUIRED

Takeda Patient Support Enrollment

By signing below, I am electing to enroll in the Services and direct all disclosures of my Information in connection with such Services (which may include, but is not limited to, verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance).

Signature of Patient (Required)/***Legal Representative Signature** Date

OPTIONAL

Consent for Marketing Information

By signing below, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided above. I understand that this consent will be in effect until I cancel such authorization.

Signature of Patient (Required)/***Legal Representative Signature** Date

*Required only if applicable.

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.

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.

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.

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.

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.

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**.