Mepsevii™
(vestronidase alfa-vjbk)
injection, for intravenous use
10 mg/5 mL (2 mg/mL)

UltraCare™

UPON ENROLLMENT, AN ULTRACARE GUIDE WILL:

- Partner with your enrolled patient and will remain dedicated to that patient
- Contact the patient or caregiver to review insurance coverage and support programs
- Assess the patient's eligibility for available financial assistance programs

STEPS TO SUCCESSFUL ENROLLMENT IN ULTRACARE

Below are the most critical steps for ensuring complete and timely enrollment so that your patients can fully benefit from the UltraCare Program:

1 GET STARTED

Select the preferred method of communication between the UltraCare Guide and the patient/caregiver

2 SELECT SITE OF CARE (SOC)

Choose the SOC for the administration of the medication:

- Home infusion with the home health nursing assistant
- Prescriber's office administration
- Outpatient hospital setting

3 VERIFY INSURANCE

- Provide a copy of all the patient's **MEDICAL** and **PRESCRIPTION** cards, front and back
- Indicate if the patient does not have health insurance (both medical and pharmacy)

4 SPECIFY PRESCRIPTION

- Select Fast Start Prescription (FSP, 2-month supply only) and/or Commercial Prescription (mandatory for FSP eligibility)
- All patients are eligible for FSP, and will receive a set amount of no-cost product prior to starting commercial therapy
- This is a true prescription—a physician's wet signature and date are required

5 OBTAIN CONSENT

The patient's signature is required to allow protected health information (PHI) to be shared by third parties with Ultragenyx to facilitate access such as:

- Benefits investigation
- Prior authorization
- Specialty pharmacy provider prescription transfer
- Home Infusion Agency
- Additional services provided by UltraCare, including insurance coverage, financial assistance, and patient support programs

If the patient wants to opt out of the patient consent section, inform the UltraCare team verbally on the phone or in writing to the address on the reverse side of this page.

INDICATION

MEPSEVII is a recombinant human lysosomal beta glucuronidase indicated in pediatric and adult patients for the treatment of Mucopolysaccharidosis VII (MPS VII, Sly syndrome).

Limitations of Use

The effect of MEPSEVII on the central nervous system manifestations of MPS VII has not been determined.

BOXED WARNING AND ADDITIONAL IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

- **Anaphylaxis has occurred with MEPSEVII administration, as early as the first dose, therefore appropriate medical support should be readily available when MEPSEVII is administered.**
- **Closely observe patients during and for 60 minutes after MEPSEVII infusion.**
- **Immediately discontinue the MEPSEVII infusion if the patient experiences anaphylaxis.**

Adverse Reactions

- In a clinical trial, the most common adverse reactions occurring with MEPSEVII treatment included infusion site extravasation, diarrhea, rash, anaphylaxis, infusion site swelling, peripheral swelling, and pruritus.
- One patient experienced a febrile convulsion during MEPSEVII treatment.

Use in Specific Populations

- There are no available data on MEPSEVII use in pregnant women to determine a drug-associated risk of adverse developmental outcomes.
- There are no data on the presence of MEPSEVII in either human or animal milk, the effects on the breastfed infant, or the effects on milk production.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Ultragenyx at 1-888-756-8657.

Please see accompanying full Prescribing Information, including the **BOXED WARNING**, for a complete discussion of the risks associated with MEPSEVII.

ultragenyx pharmaceutical

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Patient Start Form

Toll-free line: 888-756-8657 **Fax:** 415-723-7474
Address: 5000 Marina Boulevard, Brisbane, CA 94005

1 PATIENT INFORMATION: Remember to choose your preferred contact method

First, Middle, Last Name _____ Gender ☐ Male ☐ Female
DOB (MM/DD/YYYY) _____ Last 4 digits of Social Security # _____
Street Address _____ City _____ State _____ ZIP Code _____
Home Phone (___) _____ Work (___) _____ Mobile (___) _____
Best Time to Contact _____ Preferred Method of Contact ☐ Home ☐ Work ☐ Mobile ☐ Text ☐ Email
Preferred Language _____ Email _____
Caregiver Name (First and Last) _____ Relationship to Patient _____ Caregiver phone (___) _____

2 PRESCRIBER INFORMATION: Be sure to choose your preferred Site of Care (SOC)

☐ Home Infusion ☐ Office Administration ☐ Outpatient Hospital Setting Infusion Site Name _____
First and Last Name _____
Street Address _____ City _____ State _____ ZIP Code _____
Office Phone (___) _____ Fax _____ Email _____
Office Contact Name/Title _____ Office Contact Phone (___) _____
State License # _____ NPI # _____
☐ Site of Care (SOC) is Different Than the Prescriber SOC Name _____ SOC Address _____

"The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber."

3 INSURANCE INFORMATION: Remember to provide copies of patient's MEDICAL and PRESCRIPTION cards

☐ Patient Does Not Have Health Insurance

Primary Insurance Name _____	Secondary Insurance Name _____	Prescription Card Name _____
Policyholder Name _____	Policyholder Name _____	Policyholder Name _____
Relationship to Patient _____	Relationship to Patient _____	Relationship to Patient _____
Group ID # _____	Group ID # _____	Member ID # _____
Employer Name _____	Employer Name _____	
Member ID # _____	Member ID # _____	

☐ Provide Copies of All **MEDICAL** and **PRESCRIPTION** Cards–Front and Back (Primary and Secondary, Supplemental Coverage) [No Need to Populate This Section]

4 MEPSEVII™ (vestronidase alfa-vjbk) PRESCRIPTION INFORMATION: Select ICD code and type of prescription

☐ ICD-10 E76.29 ☐ Other _____

4 mg/kg IV QOW. Dilute calculated dose with 0.9% sodium chloride 1:1 to be infused over approximately 4 hours.
Please see accompanying full Prescribing Information for additional information.

Fast Start Prescription (2 Month Supply Only)

MEPSEVII 10-mg/5-mL (2-mg/mL) single-dose vial

Patient's Weight _____ kg **Date Taken** _____

Prescriber Signature _____ Date _____
(No Stamps) Dispense as Written
Prescriber Signature _____ Date _____
(No Stamps) Substitution Permitted

For all naïve to commercial therapy, patients and product must be sent to the HCP for administration at office, and cost will not be passed along to patient.

Commercial Prescription

MEPSEVII 10-mg/5-mL (2-mg/mL) single-dose vial Refills _____

Patient's Weight _____ kg **Date Taken** _____

Prescriber Signature _____ Date _____
(No Stamps) Dispense as Written
Prescriber Signature _____ Date _____
(No Stamps) Substitution Permitted

*The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

Concurrent Medications _____ Special Instructions _____ Special Precautions (eg, allergies): _____

☐ Prescriber: Please check here to authorize ancillary supplies such as needles, syringes, sterile water, etc as needed to administer the therapy.
☐ RN visit to provide education related to therapy, disease state, and nurse administration of MEPSEVII to include dosing and titration as per prescriber order.

"I authorize Ultragenyx to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan."

5 PATIENT CONSENT TO SHARE PROTECTED HEALTH INFORMATION (PHI) AND SIGNATURE

I authorize each of my physicians, pharmacists, including any specialty pharmacies and other health care providers and each of my health insurers to disclose my PHI, including but not limited to medical records, information related to my medical condition and treatment, financial, lab values, insurance coverage information, my name, address, telephone number, and last 4 digits of Social Security number to Ultragenyx Pharmaceutical Inc., and its agents, contractors, and assignees to use and disclose my PHI to enroll me in, and contact me about UltraCare Patient Services, provide case management through telephone or electronic communications to assist with adherence to my medication regimen, and work with third parties to provide community resources and referrals. Third-party vendors, such as specialty pharmacies may receive financial remuneration in exchange for data, product support services, reimbursement services, etc. This authorization expires one year from the date of execution, or one year after the date of my last prescription, whichever is later unless a shorter period is required by state law. I understand I may refuse to sign this authorization and that my treatment, payment, enrollment, or eligibility for benefits, including my access to therapy, is not conditioned on my signing this authorization. I understand that revoking this authorization will not affect the ability to use and disclose PHI received prior to receipt of notification that I wish to discontinue my participation in the program. I understand that I may revoke this authorization at any time by verbally or writing to the address listed at the top of this form. Once authorization has been revoked or expired, I understand my future PHI will not be disclosed. I understand that my PHI will not be used or disclosed for any other purposes, unless permitted by law, than for the purposes stated above. Information disclosed pursuant to this authorization or provided to a third party may no longer be protected by federal privacy laws.

Patient Signature _____ Date _____
Parent/Guardian Signature *(If patient is a minor)* _____ Date _____

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