PART III: CONSUMER INFORMATION

Pr VPRIV®
(VEE-priv)
velaglucerase alfa

This leaflet is part III of a three-part "Product Monograph" published when VPRIV was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VPRIV. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
VPRIV is an enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease.

What it does:
Gaucher disease is genetic. Patients with Gaucher disease do not produce enough of their own enzyme, glucocerebrosidase, which breaks down a type of lipid (fat) called glucocerebroside. The reduced enzyme levels in patients cause this lipid to collect in white blood cells in some organs including the brain, bone marrow, liver and spleen. Treatment with VPRIV helps replace the low enzyme levels, which helps reduce the lipid deposits.

When it should not be used:
Do not use VPRIV if you are allergic (hypersensitive) to velaglucerase alfa or any of the other nonmedicinal ingredients.

What the medicinal ingredient is:
The active ingredient in VPRIV is velaglucerase alfa. Velaglucerase alfa is an enzyme similar to the naturally occurring human enzyme glucocerebrosidase.

What the important nonmedicinal ingredients are:
The other ingredients are: citric acid monohydrate, polysorbate 20, sodium citrate dihydrate, and sucrose.

What dosage forms it comes in:
400 U/vial, packed powder for solution for injection. After reconstitution, each vial contains 100 U/mL.

WARNINGS AND PRECAUTIONS

BEFORE you use VPRIV talk to your doctor or pharmacist if:

- **You have previously experienced an infusion-related reaction or allergic reaction with other ERT for Gaucher disease.**

Hypersensitivity reactions including symptoms consistent with anaphylaxis (a severe allergic reaction) such as a tightening of the airways going into the lungs and shortness of breath have been observed in some patients treated with VPRIV.

As with any intravenous protein product, allergic reactions are possible.

Appropriate medical support should be readily available when VPRIV is administered.

Treatment with VPRIV should be approached with caution in patients who have had an allergic reaction to the active ingredient or the other medicinal ingredients in the drug product or to other enzyme replacement therapy.

If you are treated with VPRIV you may experience side effects during or following an infusion. This is known as an infusion related reaction and can sometimes be severe.

Infusion related reactions include headache, dizziness, low or high blood pressure, nausea, tiredness, and fever. If you have an infusion-related reaction, tell your doctor immediately.

If you have an infusion-related reaction you may be given additional medicines to treat or help prevent future reactions. These medicines may include antihistamines, antipyretics (for treating fever), and corticosteroids.

If the infusion-related reaction is severe, your doctor will stop the intravenous infusion immediately and start giving you appropriate medical treatment.

Most of the time, you can still be given VPRIV even if these symptoms occur.

INTERACTIONS WITH THIS MEDICATION

There is no known interaction of VPRIV with other medicines.

PROPER USE OF THIS MEDICATION

Treatment with VPRIV should be supervised by a physician or other experienced health care provider.

Usual dose:
After reconstitution, VPRIV has to be diluted in 100 mL 0.9% sodium chloride solution before use. The usual dose is an infusion of 60 U/kg. Doses less than 60 U/kg also have been used (15 U/kg up to 60 U/kg). After dilution VPRIV is given through a vein (drip feed). The infusion will normally last for 1 hour and will be given every other week.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you have missed a dose, please contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, VPRIV can cause side effects, although not everybody experiences them. Most side effects are mild to moderate and generally are associated with the infusion; however some side effects may be serious and may need treatment. Over time the number of these infusion-related reactions generally decreases. If you have any of these side effects talk to you doctor immediately.

Very common side effects (more than 1 per 10 patients) are:

- Headache
- Dizziness
- Bone pain
- Joint pain
- Back pain
- Abdominal pain
- Infusion-related reaction
- Weakness/loss of strength/fatigue
- Fever/body temperature increased
- Colds and coughs

Common side effects (more than 1 per 100 patients) are:

- Nausea
- Decreased blood pressure
- Increased blood pressure
- Neutralizing antibody positive
- Flushing
- Rapid heart beat
- Rash/hives

In clinical trials, the most serious adverse reactions observed were allergic reactions. If you have an allergic reaction following administration of VPRIV, contact your doctor immediately.

This is not a complete list of side effects. For any unexpected effects while taking VPRIV, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach of children. Store under refrigeration at 2°C to 8°C (36°F to 46°F) in the original outer packaging. Do not freeze. Protect from light. Do not use after the expiration date on the vial.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Paladin Labs Inc., at: 1-888-867-7426.

This leaflet was prepared by Shire Human Genetic Therapies, Inc.

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