

# iMedix: Your Personal Health Advisor.

## Roctavian 2 X 10Exp13 Vg/ML Intravenous Suspension

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  - **Indications:**
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### Description

Side Effects Nausea, tiredness, headache, or vomiting may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. This medication may rarely cause serious (possibly fatal) liver disease. Tell your doctor right away if you have any symptoms of liver problems, such as: nausea/vomiting that doesn't stop, loss of appetite, pain/swelling in the stomach/abdomen, yellowing eyes/skin, dark urine. After receiving valoctocogene roxaparvovec, if your body makes too much clotting protein, this may increase your risk of very serious (possibly fatal) problems from blood clots (such as heart attack, stroke, blood clots in the lungs or legs). Get medical help right away if you have: shortness of breath/rapid breathing, chest/jaw/left arm pain, unusual sweating, confusion, sudden dizziness/fainting, pain/swelling/warmth in the groin/calf, sudden/severe headaches, trouble speaking, weakness on one side of the body, sudden vision changes. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses This medication is used to treat a certain blood clotting disease (hemophilia A). Hemophilia A is a genetic disorder caused by lack of a certain clotting protein (factor VIII), or caused by clotting proteins that do not work properly. Valoctocogene roxaparvovec is known as gene therapy. It works by helping your body make normal factor VIII. This effect may decrease bleeding problems due to hemophilia A. How to use Roctavian 2 X 10Exp13 Vg/ML Intravenous Suspension Read the Patient Information Leaflet if available from your pharmacist before you receive valoctocogene roxaparvovec. If you have any questions, ask your doctor or pharmacist. This medication is given by slow injection into a vein as directed by the doctor. It is given as a one-time dose. The dosage is based on your body weight. Infusion reactions may happen while you are receiving this medication and for some time after the infusion. Your health care professional will closely monitor you during the infusion and for at least 3 hours afterward. Tell your doctor or nurse right away if you have symptoms such as runny nose, coughing, lightheadedness, fever, chills, shivering, nausea, diarrhea, itching, or trouble breathing. Your doctor may give



you other medications or slow down or temporarily stop the infusion. Precautions Before receiving valoctocogene roxaparvovec, tell your doctor or pharmacist if you have any allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before receiving this medication, tell your doctor or pharmacist your medical history, especially of: alcohol use, blood clots (for example, in the legs or lungs), heart problems (such as irregular heartbeat, previous heart attack), current infection (such as hepatitis B or C, infection of the nose/throat/airways), liver problems (including cirrhosis, fatty liver disease, liver fibrosis), stroke. Use of alcohol after receiving this treatment may increase your risk for liver problems. Avoid alcohol for at least 1 year after you receive this treatment. Consult your doctor or pharmacist for more information. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). This medication is not usually used by women. It is unlikely to be used during pregnancy or breast-feeding. Consult your doctor if you have any questions about this medication. Men with female partners of childbearing age should use reliable forms of birth control for 6 months after treatment. If your partner becomes pregnant or thinks she may be pregnant, tell the doctor right away. Do not donate sperm for 6 months after treatment. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Lab and/or medical tests (such as liver function, factor VIII activity and inhibitor levels) must be done before you start receiving this treatment and after you receive it. Keep all medical and lab appointments. Consult your doctor for more details. After receiving this treatment, do not donate blood, organs, tissues, or cells. Not applicable. Not applicable. This type of product is given in a hospital or clinic and will not be stored at home. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

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## Side Effects

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## Uses

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## Interactions

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**Other Details**

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