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Etelcalcetide Solution

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Description

Side Effects Nausea or vomiting may occur. If either of these effects lasts or gets 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. Etelcalcetide can cause low calcium blood levels. Your doctor will check your calcium levels before you start using this medication and while you are using it. Tell your doctor right away if you have any symptoms of low calcium levels, such as numbness/tingling in the hands/feet/face, muscle spasms, seizures, unusual tiredness, fast/irregular/pounding heartbeat. Tell your doctor right away if you have any serious side effects, including: black/bloody stools, stomach/abdominal pain, vomit that contains blood or looks like coffee grounds, symptoms of heart failure (such as shortness of breath, swelling ankles/feet, unusual tiredness, unusual/sudden weight gain). Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, severe dizziness, fainting. 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. 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 increased amounts of a certain hormone (parathyroid) in people with long-term kidney disease who are on dialysis. Dialysis treatment usually causes higher than normal amounts of certain substances (such as parathyroid hormone, calcium, phosphorus) in your body. This medication works by decreasing how much parathyroid hormone your body makes. This effect helps lower calcium and phosphorus levels in your blood. Having the right amounts of parathyroid hormone, calcium, and phosphorus in your body can help prevent bone problems. How to use Etelcalcetide Solution This medication is given by injection into a vein as directed by your doctor, usually 3 times each week at the end of dialysis treatment. The dosage is based on your medical condition and response to treatment. To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. If you miss a regularly scheduled dialysis treatment, you should not receive this medication until the end of your next dialysis treatment. If your doctor is switching you from treatment with cinacalcet (a different medication used to decrease parathyroid hormone) to this medication, the cinacalcet

should be stopped at least 7 days before starting etelcalcetide. Precautions Before receiving etelcalcetide, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: stomach/intestinal/esophagus problems (such as bleeding, heartburn, ulcers), seizures. Etelcalcetide may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using etelcalcetide, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Older adults may be more sensitive to the side effects of this drug, especially QT prolongation (see above). During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is unknown if this medication passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding. 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. This medication should not be used along with cinacalcet. Doing so may increase the risk of side effects (especially low calcium levels). See also How to Use section. 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. Do not share this medication with others. Lab and/or medical tests (such as parathyroid hormone, calcium, phosphorus levels) must be done before you start using this medication and while you are using it. Keep all medical and lab appointments. It is important to get each dose of this medication as scheduled. If you miss a dose, ask your doctor or pharmacist right away for a new dosing schedule. Not applicable. This medication is given in a hospital or clinic or doctor's office and will not be stored at home.

Side Effects

Uses

Interactions

Other Details
