Package leaflet: Information for the patient

Parsabiv 2.5 mg solution for injection
Parsabiv 5 mg solution for injection
Parsabiv 10 mg solution for injection
etelcalcetide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Parsabiv is and what it is used for

Parsabiv contains the active substance etelcalcetide, which reduces parathyroid hormone known as PTH.

Parsabiv is used to treat secondary hyperparathyroidism in patients with serious kidney disease who need haemodialysis to clear their blood of waste products.

In secondary hyperparathyroidism too much PTH is produced by the parathyroid glands (four small glands in the neck). “Secondary” means that the hyperparathyroidism is caused by another condition, e.g. kidney disease. Secondary hyperparathyroidism can cause the loss of calcium from the bones, which can lead to bone pain and fractures and problems with blood and heart vessels. By controlling the levels of PTH, Parsabiv helps to control calcium and phosphate in your body.

2. What you need to know before you use Parsabiv

Do not use Parsabiv if you are allergic to etelcalcetide or any of the other ingredients of this medicine (listed in section 6).

Do not use Parsabiv if you have very low levels of calcium in your blood. Your doctor will monitor your blood calcium levels.

Warnings and precautions
Before you are given Parsabiv, tell your doctor if you have or have ever had:
- heart problems, such as heart failure or arrhythmias (abnormal heart rhythm);
- seizures (fits or convulsions).

Parsabiv reduces calcium levels. Please tell your doctor if you have spasms, twitches, or cramps in your muscles, or numbness or tingling in your fingers, toes or around your mouth or seizures, confusion or loss of consciousness while being treated with Parsabiv.

Low calcium levels can cause abnormal heart rhythm. Tell your doctor if you experience an unusually fast or pounding heartbeat, if you have heart rhythm problems or heart failure or if you take medicines that can cause heart rhythm problems, while receiving Parsabiv. For additional information see section 4.

Very low levels of PTH over long periods can result in a type of abnormal bone structure known as adynamic bone which can only be diagnosed by biopsy. Your PTH levels will be monitored during treatment with Parsabiv and your dose of Parsabiv may be reduced if your PTH levels become very low.

Children and adolescents
It is not known whether Parsabiv is safe and effective in children less than 18 years of age as it has not been studied in these patients.

Other medicines and Parsabiv
Tell your doctor if you are taking, have recently taken or might take any other medicines, particularly cinacalcet or any other medicines that lower serum calcium.

You should not receive Parsabiv together with cinacalcet.

Pregnancy and breast-feeding
Parsabiv has not been tested in pregnant women. It is not known whether Parsabiv can harm your unborn baby. Tell your doctor if you are pregnant, think you may be pregnant, or plan to get pregnant when taking Parsabiv. You and your doctor should decide if you should use Parsabiv.

It is not known whether Parsabiv can pass into breast milk. Tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding, or whether to stop taking Parsabiv, considering the benefit of breast-feeding to the baby and the benefit of Parsabiv to the mother.

Driving and using machines
Parsabiv has no or negligible influence on the ability to drive and use machines. However certain symptoms of low calcium levels (such as fits or convulsions) can affect your ability to drive or operate machinery.

Important information about some of the ingredients of Parsabiv
This medicine contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially ‘sodium-free’.

3. How to use Parsabiv

The recommended starting dose for Parsabiv is 5 mg. It will be given by a doctor or nurse at the end of your haemodialysis treatment through the tube (bloodline) that connects you to the haemodialysis machine. Parsabiv will be given 3 times per week. The dose may be increased up to 15 mg or lowered down to 2.5 mg depending on your response.

You may need to take calcium and vitamin D supplements while being treated with Parsabiv. Your doctor will discuss this with you.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you start to get numbness or tingling around your mouth or in your extremities, muscle aches or cramps and seizures (fits), you should tell your doctor immediately. These may be signs that your calcium levels are too low (hypocalcaemia).

Very common: may affect more than 1 in 10 people
- Nausea
- Vomiting
- Diarrhoea
- Muscle spasms
- Low calcium levels in blood with no symptoms

Common: may affect up to 1 in 10 people
- Low calcium levels in blood with symptoms such as tingling around the mouth or in the extremities, muscle aches or cramps and seizures (fits)
- High potassium levels in blood
- Low phosphate levels in blood
- Headache
- Numbness or tingling sensation
- Worsening heart failure
- Disturbances in the heart's electrical activity seen as QT prolongation on electrocardiogram
- Low blood pressure
- Muscle pain

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Parsabiv

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Keep the vial in the outer carton in order to protect from light.

Once removed from the refrigerator:
- Parsabiv is stable for a maximum of 7 cumulative days if stored in the original carton. No special temperature storage requirements are needed.
- If removed from the original carton Parsabiv is stable for a maximum of 4 hours if protected from direct sunlight.

Do not use this medicine if you notice it has particles or it has changed colour.

For single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Parsabiv contains
- The active substance is etelcalcetide.
  Parsabiv 2.5 mg solution for injection: Each vial contains 2.5 mg of etelcalcetide in 0.5 mL solution (5 mg/mL).
  Parsabiv 5 mg solution for injection: Each vial contains 5 mg of etelcalcetide in 1 mL solution (5 mg/mL).
  Parsabiv 10 mg solution for injection: Each vial contains 10 mg of etelcalcetide in 2 mL solution (5 mg/mL).
- The other ingredients are sodium chloride, succinic acid, water for injections, hydrochloric acid, and sodium hydroxide.

What Parsabiv looks like and contents of the pack
Parsabiv is a clear and colourless liquid.

Parsabiv is a solution for injection in a vial.

Pack sizes of 1, 6, 12 and 42 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Amgen Europe B.V.
Minervum 7061
NL-4817 ZK Breda
The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu