Parsabiv®
(etelcalcetide) Injection for intravenous use
2.5mg/0.5mL | 5mg/1mL | 10mg/2mL

Parsabiv® Tool for Healthcare Professionals

Indication

Parsabiv® (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Limitations of Use:

Parsabiv® has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Important Safety Information

Parsabiv® is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Please see additional Important Safety Information on last page.

Before you initiate Parsabiv®

Switching to Parsabiv® from oral cinacalcet

Ensure your patient discontinues use of oral cinacalcet for at least 7 days prior to starting Parsabiv®[1]

Discontinue for at least 7 days

- Initiate Parsabiv® after day 7, if corrected serum calcium is at or above the lower limit of normal*

The approved starting dose

Initiate Parsabiv® at 5 mg, 3 times per week[1]

- Do not administer Parsabiv® more frequently than 3 times per week[1]
- Ensure corrected serum calcium is at or above the lower limit of normal prior to Parsabiv® initiation, a dose increase, or reinitiation after dosing interruption[1]
- If a regularly scheduled hemodialysis treatment is missed, DO NOT administer any missed doses. Resume Parsabiv® at the end of the next hemodialysis treatment at the prescribed dose[1]
- If doses of Parsabiv® are missed for more than 2 weeks, reinitiate Parsabiv® at the recommended starting dose of 5 mg (or 2.5 mg if that was the patient's last dose)[1]

5 mg starting dose | **3x** a week | **IV after rinse back or During rinse back**

*Lower limit of reference range in phase 3 trials was 8.3 mg/dL.[1,2]

Important Safety Information

Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

Please see additional Important Safety Information on last page.

How to monitor and titrate Parsabiv®

Check their labs and know where they stand[1]

	PTH	Corrected Serum Calcium
Lab measurements after initiation or dose adjustment	after 4 weeks	at 1 week
Lab measurements once maintenance dose is established	per clinical practice	every 4 weeks

Adjust dose based on PTH and corrected serum calcium[1]

Start at 5 mg—then titrate up or down

Reductions too great? Titrate down:

- Decrease or temporarily discontinue Parsabiv® when PTH is below target range
- Consider decreasing or temporarily discontinuing Parsabiv®, or use concomitant therapies,* when corrected serum calcium is below lower limit of normal† but ≥ 7.5 mg/dL without symptoms of hypocalcemia

Need greater reductions? Titrate up:

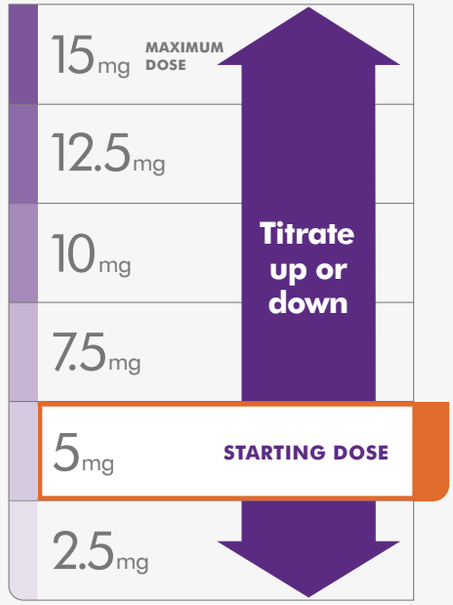
- Increase the dose of Parsabiv® in 2.5 mg or 5 mg increments until PTH is within recommended target range and corrected serum calcium is within normal range
- Increase no more frequently than every 4 weeks up to a maximum dose of 15 mg three times per week

Reinitiating Parsabiv®:

- If dose is stopped, reinitiate Parsabiv® at a lower dose when PTH is within target range and hypocalcemia has been corrected

*Concomitant therapies include calcium, calcium-containing phosphate binders, and/or vitamin D sterols or increases in dialysate calcium concentration.

†Lower limit of reference range in phase 3 trials was 8.3 mg/dL.[1,2]



Important Safety Information

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Please see additional Important Safety Information on last page.

Remember to follow these storage, handling, and administration tips

Parsabiv® is available in 3 different, single-use, single-dose vials[1]

2.5mg/0.5mL | 5mg/1mL | 10mg/2mL

Vials shown are not actual size.

Protect from light[1]

- **DO NOT remove the carton lid**
- Keep Parsabiv® in the original closed carton, in the refrigerator, until you're ready to use it (2°C to 8°C [36°F to 46°F])
- Once removed from the refrigerator:
  - Use within 7 days if stored in the original carton
  - Use within 4 hours and do not expose to light if removed from original carton

Keep cold[1]

- Once removed from the refrigerator, **DO NOT** expose to temperatures above 25°C (77°F)
  - **DO NOT** place Parsabiv® on warm/hot surfaces

Managing calcium in patients taking Parsabiv®[1]

≥ 8.3 mg/dL*

Initiate Parsabiv®

- Do not initiate Parsabiv® if corrected serum calcium is less than the lower limit of normal*
- **Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®.** Educate patients on the symptoms of hypocalcemia and advise them to contact a healthcare provider if they occur

< 8.3 mg/dL to **≥ 7.5 mg/dL*** without symptoms of hypocalcemia

Adjust Treatment as Needed

- **Consider decreasing or temporarily discontinuing Parsabiv® or use concomitant therapies to increase corrected serum calcium** (including calcium, calcium-containing phosphate binders, and/or vitamin D sterols or increases in dialysate calcium concentration)

< 7.5 mg/dL or with symptoms of hypocalcemia

Withhold Parsabiv® and Monitor

- **Stop Parsabiv® and treat hypocalcemia**
- **Start or increase calcium supplementation** (including calcium, calcium-containing phosphate binders, and/or vitamin D sterols or increases in dialysate calcium concentration)

- **Throughout the studies, dialysate calcium concentration could be adjusted but had to remain ≥ 2.25 mEq/L[1]**
- **Significant lowering of serum calcium can cause paresthesias, myalgias, muscle spasms, seizures, QT interval prolongation, and ventricular arrhythmias[1]**

*Lower limit of reference range in phase 3 trials was 8.3 mg/dL.[1,2]

When cCa returns ≥ 8.3 mg/dL* — **Reinitiate Parsabiv®**

- **When corrected serum calcium levels are within normal limits, symptoms of hypocalcemia have resolved**, and predisposing factors for hypocalcemia have been addressed, reinitiate Parsabiv® at a dose 5 mg lower than the last administered dose. If patient's last administered dose of Parsabiv® was 2.5 mg or 5 mg, reinitiate at a dose of 2.5 mg

Please see additional Important Safety Information on last page.

Important Safety Information

Contraindication: Parsabiv® (etelcalcetide) is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Hypocalcemia: Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Concurrent administration of Parsabiv® with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to Parsabiv® should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv®. Do not initiatein patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv®. Once the maintenance dose has been established, measure PTH per clinical practice.

Worsening Heart Failure: In Parsabiv® clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv® for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding: In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv®.

Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv®. Monitor patients for worsening of common Parsabiv® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® therapy.

Adynamic Bone: Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions: In clinical trials of patients with secondary HPT comparing Parsabiv® to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

Please see Parsabiv® full Prescribing Information.

References

1. Parsabiv® (etelcalcetide) prescribing information, Amgen.
2. Block GA, Bushinsky DA, Cunningham J, et al. Effect of etelcalcetide vs placebo on serum parathyroid hormone in patients receiving hemodialysis with secondary hyperparathyroidism: two randomized clinical trials. *JAMA*. 2017;317:146-155.

Visit **ParsabivHCP.com** for more information.

AMGEN®

Parsabiv®
(etelcalcetide) Injection for intravenous use
2.5mg/0.5mL | 5mg/1mL | 10mg/2mL

Patient Name _____

The prescriber has made the decision to initiate Parsabiv® (etelcalcetide).

Please use this as a guide to communicate your decision with your care team (including dietitian).

A What are the reasons this patient is or is not "adequately managed" on current therapy/therapies?

B What are the clinical reasons you believe this patient may be appropriate for Parsabiv®?

C What are your patient's current labs? PTH _____, cCa _____, and P _____

What are the preferred labs for Parsabiv® initiation?

PTH _____, cCa _____, and P _____

Now that Parsabiv® has been prescribed, tasks to be considered:

- ☐ All dialysis provider authorization forms/paperwork to be completed by _____.
- ☐ Confirm Parsabiv® inventory at facility.
- ☐ Place Parsabiv® order on _____.
- ☐ If patient was on oral cinacalcet, patient discontinued on _____.
- ☐ Start Parsabiv® on _____ at a dose of _____.

Indication

Parsabiv® (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Limitations of Use:

Parsabiv® has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Important Safety Information

Parsabiv® is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Please see additional Important Safety Information on last page.

PTH = parathyroid hormone; cCa = corrected calcium; P = phosphate.

Parsabiv® (etelcalcetide) Injection for intravenous use

2,5mg/0,5mL | 5mg/1mL | 10mg/2mL

Important Safety Information

Contraindication: Parsabiv® (etelcalcetide) is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Hypocalcemia: Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Concurrent administration of Parsabiv® with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to Parsabiv® should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv®. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv®. Once the maintenance dose has been established, measure PTH per clinical practice.

Worsening Heart Failure: In Parsabiv® clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv® for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding: In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv®.

Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv®. Monitor patients for worsening of common Parsabiv® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® therapy.

Adynamic Bone: Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions: In clinical trials of patients with secondary HPT comparing Parsabiv® to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

Please see Parsabiv® full Prescribing Information.

AMGEN®

Parsabiv® (etelcalcetide) Injection for intravenous use

2,5mg/0,5mL | 5mg/1mL | 10mg/2mL