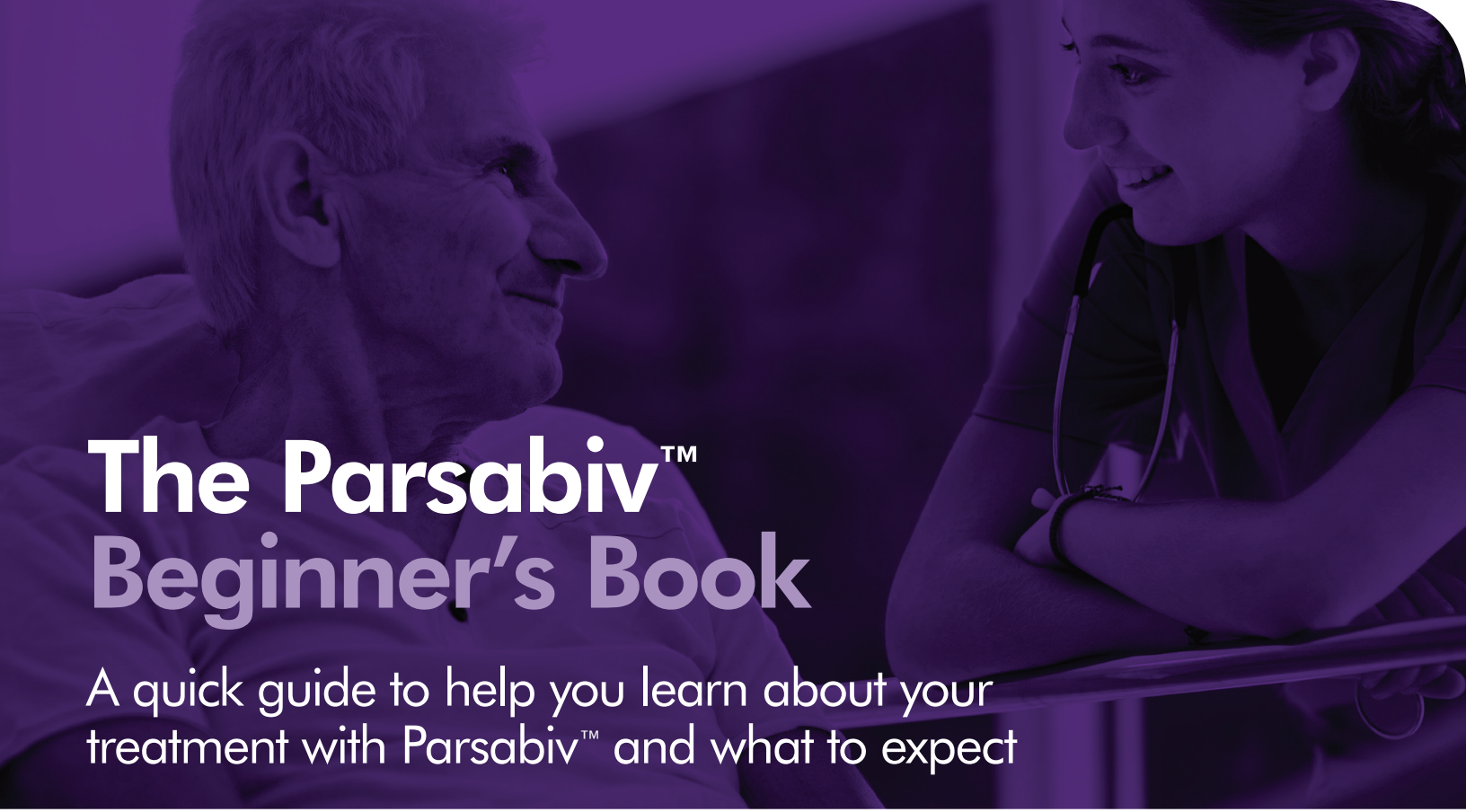


The Parsabiv™ Beginner's Book

A quick guide to help you learn about your treatment with Parsabiv™ and what to expect

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

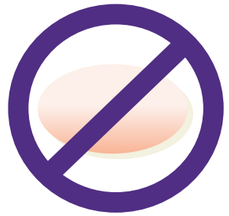
Parsabiv™ is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including pruritic rash, urticaria, and face edema, have occurred.

Please see additional Important Safety Information on page 10.

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

Why did my doctor prescribe Parsabiv™?

It's a treatment for a condition called secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis[1]



Parsabiv™ is not a pill.[1]

It's given intravenously.[1]

It's given by your dialysis care team at the end of your hemodialysis session through the tube (bloodline) that connects you to the machine.[1]
Keep in mind: You shouldn't be started on Parsabiv™ if you have low calcium levels. (You can ask your doctor about normal ranges for calcium.)

Pill shown is not actual size

Important Safety Information

Parsabiv™ lowers serum calcium and can lead to hypocalcemia, sometimes severe. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias secondary to hypocalcemia. Closely monitor corrected serum calcium in patients with these conditions on Parsabiv™.

Please see additional Important Safety Information on page 10.

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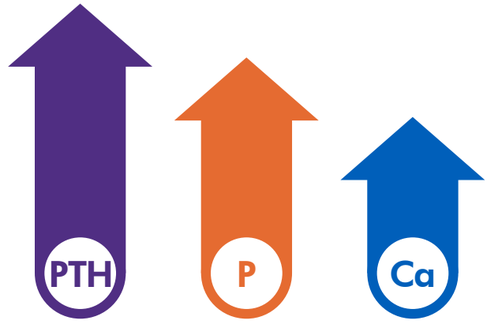
What is secondary HPT?

When your kidneys fail, your parathyroid glands can make too much parathyroid hormone (PTH)[2,3]

Too much PTH can make your phosphorus and calcium levels go up[4-6]



What's the goal?

Your dialysis care team may have goal ranges for your PTH, phosphorus, and calcium levels.

Parsabiv™ is part of their plan to get and keep your levels in range.

P = phosphorus; Ca = calcium.

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 page 10.

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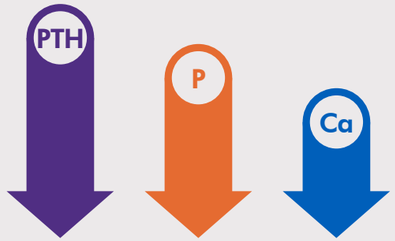
Why Parsabiv™?

Parsabiv™ acts on your parathyroid glands and causes them to release less PTH[1]

When PTH goes down, your bones release less phosphorus and calcium.[2,4]

One treatment that can help lower the 3 key levels[1]



Your doctor may also prescribe other medicines to treat your secondary HPT:

- Phosphate binders* help you absorb less phosphorus from the food you eat[4]
- Certain types of vitamin D* may help lower your PTH. This medicine is usually given to you through the dialysis machine, or you may take it as a pill[3,7]

*Phosphate binders and vitamin D are available by prescription.

How will I get Parsabiv™?

Parsabiv™ is given at the end of your hemodialysis session through the tube (bloodline) that connects you to the machine[1]

IV delivery

Your nurse or other healthcare provider will administer it for you.

IV = intravenous.

Important Safety Information

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.

Please see additional Important Safety Information on page 10.

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What if my dialysis care team is switching me from Sensipar® (cinacalcet) to Parsabiv™?

Sensipar® (cinacalcet) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis.

Sensipar® should not be used in adult patients with CKD who are not on dialysis because of an increased risk of low calcium levels.

Stop taking Sensipar® (cinacalcet)

You need to stop taking Sensipar® pills at least 7 days before you can start Parsabiv™. You cannot be on both drugs at the same time.[1]

Stop Sensipar® for 7 days before you start Parsabiv™

Parsabiv™ can be started after day 7 if your calcium is in the normal range

Pills shown are not actual size

Important Safety Information

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.

Please see additional Important Safety Information on page 10.

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

Important Safety Information for Parsabiv™ (etelcalcetide)

Contraindication: Parsabiv™ is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including pruritic rash, urticaria, and face edema, have occurred.

Hypocalcemia: Parsabiv™ lowers serum calcium and can lead to hypocalcemia, sometimes severe. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias secondary to hypocalcemia. Closely monitor corrected serum calcium in patients with these conditions 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, 3 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%), and vomiting (9% vs. 5%).

Please see accompanying Parsabiv™ full Prescribing Information.

References

1. Parsabiv™ (etelcalcetide) prescribing information, Amgen.
2. Rodriguez M, Nemeth E, Martin D. The calcium-sensing receptor: a key factor in the pathogenesis of secondary hyperparathyroidism. *Am J Physiol Renal Physiol.* 2005;288:F253-F264.
3. Komaba H, Shiizaki K, Fukagawa M. Pharmacotherapy and interventional treatments for secondary hyperparathyroidism: current therapy and future challenges. *Expert Opin Biol Ther.* 2010;10:1729-1742.
4. Goodman WG. Calcium and phosphorus metabolism in patients who have chronic kidney disease. *Med Clin North Am.* 2005;89:631-647.
5. Goodman WG. The consequences of uncontrolled secondary hyperparathyroidism and its treatment in chronic kidney disease. *Semin Dial.* 2004;17:209-216.
6. Streja E, Lau WL, Goldstein L, et al. Hyperphosphatemia is a combined function of high serum PTH and high dietary protein intake in dialysis patients. *Kidney Int Suppl (2011).* 2013;3:462-468.
7. Tentori F, Wang M, Bieber BA, et al. Recent changes in therapeutic approaches and association with outcomes among patients with secondary hyperparathyroidism on chronic hemodialysis: the DOPPS study. *Clin J Am Soc Nephrol.* 2015;10:98-109.

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What about any side effects?

You may experience side effects while taking Parsabiv™[1]

Some patients reported potential symptoms of a condition called hypocalcemia (low calcium levels), including tingling and/or numbness of the skin, muscle pain, and muscle spasms.

During studies of Parsabiv™, some patients reported other various side effects like diarrhea, nausea, and vomiting.

What if I feel side effects?

Talk to your healthcare provider right away

After talking to your healthcare provider, you can report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088 (332-1088).

FDA = Food and Drug Administration.

Important Safety Information

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.

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Does my insurance cover Parsabiv™?

What about out-of-pocket costs?

Parsabiv™ is covered by Medicare*

Your dialysis facility will bill your insurer for Parsabiv™ along with your hemodialysis treatments.

You may have out-of-pocket costs for Parsabiv™, like a co-pay or co-insurance. Depending on your circumstances, there may be programs that can help if you are having difficulty affording your medications.

AMGEN ASSIST®
SIMPLIFYING REIMBURSEMENT

For more information about coverage of Parsabiv™, talk to your social worker—or contact Amgen Assist® at 1-800-272-9376

*Coverage may vary with commercial plans and other insurers. Please contact Amgen Assist® for coverage and reimbursement support at 1-800-272-9376.

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AMGEN®

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