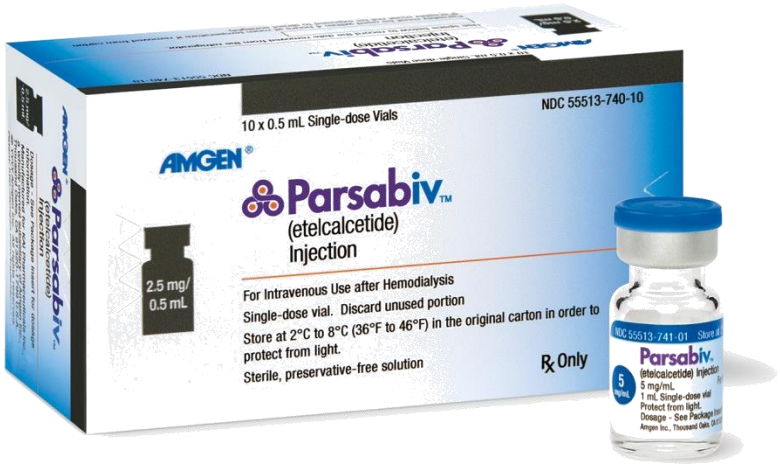
Parsabiv (etelcalcetide)



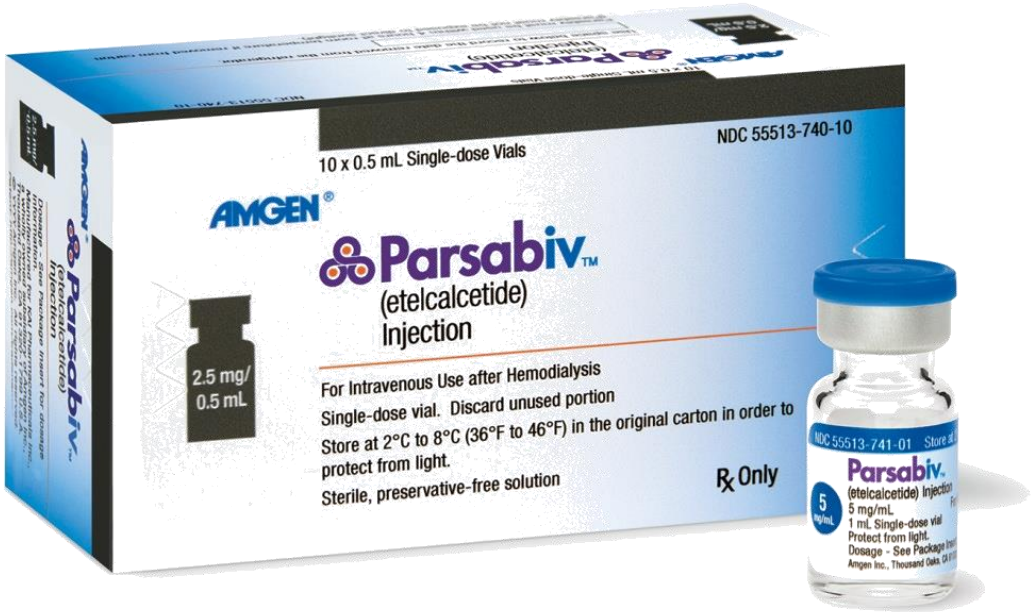
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Parsabiv
- **Generic name:** Etelcalcetide
- **Pharmacological class:** Calcimimetic
- **Strength and Formulation:** 2.5mg/0.5mL, 5mg/mL, 10mg/2mL; soln for IV inj; preservative-free
- **Manufacturer:** Amgen
- **How supplied:** Single-dose vials—10
- **Legal Classification:** Rx

Parsabiv


10 x 0.5 mL Single-dose Vials
NDC 55513-740-10
AMGEN
Parsabiv™
(etelcalcetide)
Injection
2.5 mg/
0.5 mL
For Intravenous Use after Hemodialysis
Single-dose vial. Discard unused portion
Store at 2°C to 8°C (36°F to 46°F) in the original carton in order to protect from light.
Sterile, preservative-free solution
℞ Only
NDC 55513-741-01
Parsabiv.
(etelcalcetide) Injection
5 mg/mL
1 mL Single-dose vial
Protect from light.
Dosage - See Package Insert
Amgen Inc., Thousand Oaks, CA

Indications

- **Secondary hyperparathyroidism** in adults with chronic kidney disease (CKD) on hemodialysis

Limitations of Use

- **Not recommended** in adults with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis

Dosage & Administration

- Give at the end of hemodialysis
- **Initial**: 5mg as IV bolus inj 3 times weekly
- **Maintenance**: 2.5mg–15mg 3 times weekly based on PTH target range and corrected serum calcium response within normal range
- May increase in 2.5mg or 5mg increments no sooner than every 4 weeks; max 15mg 3 times weekly

Dosage & Administration

- **Switching from cinacalcet**: 5mg
- **Monitoring and dose adjustment:** see full labeling

Considerations for Special Populations

- **Pregnancy:** Limited data to inform drug-associated risk
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Elderly:** No adjustment needed
- **Hepatic and renal impairment:** No adjustment required

Warnings/Precautions

- Risk of **hypocalcemia**
- Increased risk of **QT prolongation** and **ventricular arrhythmias** in congenital or family history of long QT syndrome or sudden cardiac death, history of QT prolongation and other predispositions; monitor closely
- Seizure disorders

Warnings/Precautions

- Measure **corrected serum calcium** prior to initiation; d**o not** start if below lower limit of normal
- Monitor serum calcium within 1 week of initiation or dose adjustment and every 4 weeks of treatment (see full labeling)
- If serum calcium is below lower limit of normal or symptoms of hypocalcemia occurs, initiate or increase calcium supplementation

Warnings/Precautions

- Monitor for **adynamic bone disease**; if PTH levels fall below target range, reduce dose (Vit.D sterols and/or etelcalcetide) or discontinue; resume at lower dose
- Monitor closely for signs of worsening **heart failure**
- Known gastritis, esophagitis, ulcers, severe vomiting: monitor for worsening GI reactions, bleeding, and ulcerations

Interactions

- See Adults
- Risk of severe **hypocalcemia** with concomitant other oral calcium sensing receptor agonist
- When switching from **cinacalcet,** discontinue cinacalcet for **at least 7 days prior to initiation**

Adverse Reactions

- Decreased blood calcium
- Muscle spasms
- Diarrhea
- Nausea
- Vomiting
- Headache
- Hypocalcemia (may be severe)
- Paresthesia

Mechanism of Action

- **Etelcalcetide** is a calcimimetic agent that modulates the calcium-sensing receptor (CaSR) and enhances activation of the receptor
- Activation of the CaSR on the parathyroid chief cells decreases PTH secretion

Clinical Studies

- **Etelcalcitide** was studied in two 26-week, randomized, double-blind, placebo controlled studies (**Study 1** and **Study 2**)
- Enrolled patients had secondary hyperparathyroidism with CKD receiving hemodialysis 3 times weekly

Clinical Studies

- Starting dose: Parsabiv 5mg 3 times weekly at the end of hemodialysis
- Titrated every 4 weeks until Week 17 to a max dose of 15mg 3 times weekly
- The **primary endpoint** was the proportion of patients with >30% reduction of PTH from baseline to efficacy assessment phase (Weeks 20–27)

Clinical Studies

- In **Study 1**, patients were randomized to receive Parsabiv (n= 254) or placebo (n=254)
- Patients taking Parsabiv had a superior response in achieving >30% reduction in PTH during EAP (77%) vs. placebo (11%)

Clinical Studies

- More patients taking Parsabiv achieved ≤300pg/mL in PTH during EAP (52%) vs. placebo (6%)
- A greater mean percent change in corrected serum calcium and serum phosphate with Parsabiv (-7.0, -8.8) vs. placebo (0.9, -3.6), respectively

Clinical Studies

- In **Study 2**, patients were randomized to receive Parsabiv (n= 255) or placebo (n=260)
- Patients taking Parsabiv had a superior response in achieving >30% reduction in PTH during EAP (79%) vs. placebo (11%)

Clinical Studies

- More patients taking Parsabiv achieved ≤300pg/mL in PTH during EAP (56%) vs. placebo (5%)
- A greater mean percent change in corrected serum calcium and serum phosphate with Parsabiv (-7.0, -7.2) vs. placebo (-0.8 -0.3), respectively

Clinical Studies

- Parsabiv decreased PTH levels regardless of baseline PTH, duration of dialysis, prior therapy of cinacalcet or vitamin D sterols

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/parsabiv/drug/34704