Medicine Shortage Communication

<Day Month 2025>

Mimpara® (cinacalcet): marketing cessation of all strengths of tablets and granules in capsules for opening

Dear Healthcare Professional,

Amgen Europe B.V, Marketing Authorization Holder for Mimpara®, is notifying healthcare professionals about <a > / <an upcoming>[1] shortage of all strengths of Mimpara® tablets <and granules in capsules for opening>. This shortage is the result of a commercial decision to cease marketing of Mimpara® in EU/EEA markets.

Overview of situation

- **Amgen has decided to stop marketing of all strengths of Mimpara tablets (30, 60, 90 mg) <and granules in capsules for opening (1, 2.5, 5 mg)> in EU/EEA markets due to commercial reasons.**
- **Discontinuation of distribution from Amgen warehouses <has taken effect> /< will take effect in <March> <September> 2025>.**

Mitigation measures

In order to manage the shortage, the MAH has engaged with the European Medicines Agency and the National Competent Authorities on mitigation measures.

Healthcare professionals should:

<Not initiate any new patients on any strength of Mimpara tablets or granules in capsules for opening.>

Switch existing patients to an alternative treatment taking into account:

> **<Different generic versions of cinacalcet tablets are currently available according to the approved indications and dosages; however, > there is no generic formulation of cinacalcet granules in capsules for opening;**
>
> **Etelcalcetide (Parsabiv) is authorised for adult patients with secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD) on haemodialysis. Etelcalcetide should not be initiated in patients until 7 days after the last dose of cinacalcet and the corrected serum calcium is at or above the lower limit of the normal range.**

For additional information consult EMA's shortage catalogue,> <your country's shortage register> <or your national competent authority.

[1] select statement in <> that applies at national level

Background on the shortage

Mimpara is indicated for:

Secondary hyperparathyroidism

Adults

Treatment of secondary hyperparathyroidism (HPT) in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy.

Paediatric population

Treatment of secondary hyperparathyroidism (HPT) in children aged 3 years and older with end-stage renal disease (ESRD) on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy (see section 4.4 of the summary of product characteristics).

Mimpara may be used as part of a therapeutic regimen including phosphate binders and/or Vitamin D sterols, as appropriate (see section 5.1).

Parathyroid carcinoma and primary hyperparathyroidism in adults

Reduction of hypercalcaemia in adult patients with:

• parathyroid carcinoma;

• primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.

Amgen has decided to stop marketing of all strengths of Mimpara tablets <and capsules> from EU/EEA markets due to commercial reasons. Amgen <has stopped> / <will stop> distributing all strengths of Mimpara tablets and capsules commercially in <Member State> in <March 2025> / <September 2025>.

Company contact point

<Enter local country contact details, point of contact, hotline, website etc>

***Annexes** (if applicable)*

Not applicable

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Mimpara® (Cinacalcet)
Marketing authorisation holder(s)	Amgen Europe B.V.
Purpose of the communication	Inform Health Care Professionals about Amgen's decision to stop commercializing Mimpara® tablets and capsules.
MSC recipients	External Stakeholders that have regular interactions with Amgen Medical (physicians, pharmacists, nurses). MSC communication to be posted on Amgen country websites, where applicable.
Member States where the MSC will be distributed	Belgium, Greece, Hungary, Slovenia, Croatia, Czech Republic, Germany, Ireland, Netherlands, Portugal, France, Slovenia, Spain. In addition, in agreement with NCAs: Austria, Cyprus, Italy, Luxembourg, Malta, Poland, Romania.

Timetable *[Delete steps which are not applicable]*	**Date**
MSC and communication plan (in English) agreed by SPOC WP	25th February 2025
MSC and communication plan (in English) agreed by MSSG	21st March 2025
Submission of translated MSCs to the national competent authorities for review	As soon as possible, but no later than 28 March 2025
Agreement of translations by national competent authorities	No later than 4 April 2025
Dissemination of MSC	In agreement with NCAs: as soon as possible, but no later than 7 April 2025 for countries where distribution stopped in March 2025. As soon as possible, but no later than 31 August 2025 in countries where distribution stops in September 2025 (BE, FR, ES, SI).