



OMEPRAZOLE Rapid Relief Capsules

A proton-pump inhibitor with rapid absorption due to the protective effect of sodium hydrogen carbonate

- **Indicated for** the treatment of reflux symptoms (e.g., heartburn, acid regurgitation) in adults (OTC status).
- The formulation contains sodium hydrogen carbonate, which protects Omeprazole against stomach acid and also accelerates its absorption.

Registered as a consumer health product

Available strengths: 20mg once daily administration on an empty stomach For OTC – short term treatment (max. 14 days)

Fast onset of action

- The formulation does not contain enteric coating and therefore it is enabling the fast absorption of Omeprazole compared to the standard delayed-release formulation.
- It is suitable for OTC and short-term treatment (can be taken for 14 consecutive days to help control symptoms).

Reference markets

- Omeprazole 20mg is OTC in most markets, with 46.5m€ sales in EU27+UK as per IQVIA (MAT Q2 2022).
- The Antacid products OTC market is large with brands like Rennie, Maalox, Gaviscon.

Regulatory pathway

- Legal basis: Article 10(3) hybrid application

Development status

- The EU DCP (European Decentralized Procedure) was submitted in March 2023.
- During a Scientific Advice session with the Medical Products Agency (MPA) in Sweden, both clinical and regulatory feasibility were confirmed.
- The product is expected to be launched in European markets in early 2025.

Partnership options

- The product is available for out-licensing in select European markets
- The product is also available for licensing outside of Europe

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