



OMEPRAZOLE Rapid Relief Capsules

Proton-pump inhibitor
with fast onset of action
due to Sodium hydrogen
carbonate

- **Indicated for** treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults
- Formulation contains Sodium hydrogen carbonate which helps faster neutralization of stomach acid and therefore protects omeprazole against stomach acid and also accelerates its absorption

Registration as
consumer health
product planned

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 fast release of Omeprazole compared to standard delayed-release formulation
- Faster increase in stomach pH compared to standard delayed-release formulation

Reference markets

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



Regulatory pathway

- Legal basis: Article 10(3) hybrid application

Development status

- EU DCP submission 03/2023; clinical/regulatory feasibility confirmed during Scientific Advice with the MPA (Sweden; RMS)
- Pilot study finished 04/2022
- Pivotal BE study results expected in Q4 2022

Partnership options

- Product is available for out-licensing in selected markets in Europe on exclusive or semi-exclusive base
- Dossier can be adjusted to markets outside Europe based on request

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