

SyrCelt[™] Esomeprazole Gastro-resistant Syrup

FOR THE TREATMENT OF PAEDIATRIC GERD

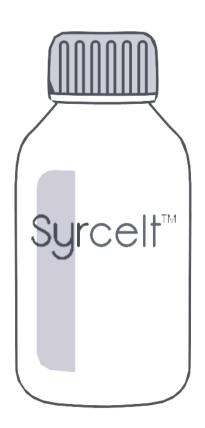
POWERED BY THE MMCR* TECHNOLOGY



INTRODUCTION OF GERD DISEASE IN CHILDREN



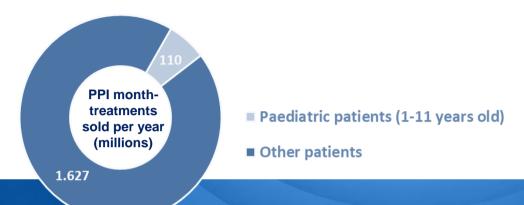
- Gastroesophageal reflux (GER) is a common and self-limiting condition.
- It is a normal physiological process defined as the retrograde flow of gastric contents into the esophagus, usually related to immaturity of the lower esophageal sphincter in the case of children.
- However, when GER becomes pathological, it can lead to frequent or severe symptoms and complications, which is then referred to as gastroesophageal reflux disease (GERD).
- Although the prevalence of GER in the first six months of life is reported to be as high as **55–73%**, a proportion (5–9%) of all infants with regurgitation have GERD.
- Symptoms that suggest GERD in infants include **poor growth** or weight gain, as well as signs of esophagitis such as irritability, feeding problems, **sleep disturbances**, crying episodes, and **anemia**.



GERD & PROTON PUMP INHIBITORS: THE MARKET



- Gastroesophageal reflux disease (GERD)
 - One of the most commonly diagnosed digestive disorders, estimated to affect 20% of the western population.
- Proton Pump Inhibators (PPI)
 - Of the available drugs to treat GERD, Proton Pump Inhibitors
 (PPI) are the most used and in the Guidelines of ESPhang.
 - Of all patients using PPIs, children between 1 and 11 years old represent 3-6% of the population.



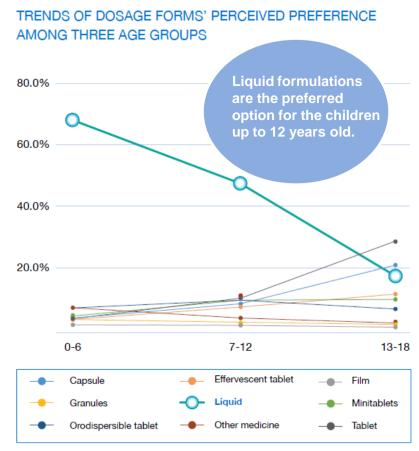
Paediatric Market size 7:

Estimated range in 2023 154.5 - \$ 360.5 Mio US\$

UNMET MEDICAL NEEDS IN PAEDITRICS



- The current approach for treating children suffering from GERD remains far from optimal.
 - Challenging for children to swallow, as most are available only as solid capsules or tablets
 - Most Solid forms do not allow for adequate weight-based dosing administration
- The advantages of a liquid formulation of PPI gastro-resistant would meet this major unmet need for the paediatric patients.



Source: Pharmaceutics 2021, 13, 730

VALUE PROPOSITION OF THE INNOVATIVE MMCR TECHNOLOGY



A CONVENIENT PPI LIQUID DOSAGE FORM





Liquid oral formulation

Designed oral pharmaceutical dosage form tailored for the pediatric population



Gastro-Resistant

Gastro-resistance is key to ensure optimal bioavailability and maintains the drug's effectiveness



Flexible dosage

Accommodates
flexible weight-based
dosing without
compromising the
medication's
effectiveness caused
by inadequate
preparation



Stable multi-dose formula

Long in-use stability upon reconstitution ensuring effectiveness in each dose

This innovative treatment will lead to rapid market penetration

THE MMCR ESOMEPRAZOLE SYRUP TECHNOLOGY For the treatment of paediatric GERD



 A gastro-resistant syrup that ensures delayed delivery to prevent degradation of API by the acidity of the stomach.

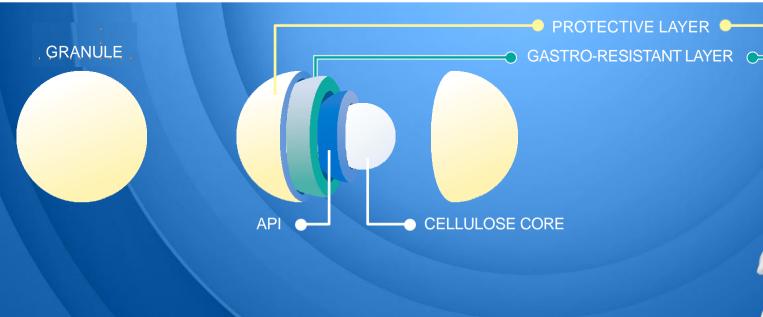
• The MMCR Technology = a combination of multilayered granules resuspended in a syrup.

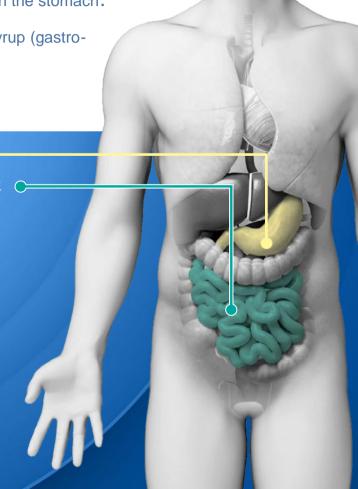
• The multiple coats on the granules :

- An external layer which ensure the stability of the granules in the syrup and which dissolves in the stomach.

An intermediate layer which protects the active ingredient from the acid environment of the syrup (gastro-resistance) and which will dissolve in the neutral pH of the intestine.

- An API-containing internal layer

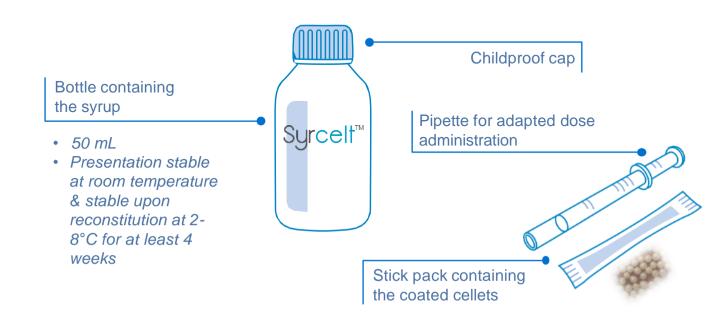




KEY PRODUCT FEATURES & RECONSTITUTION PROCESS







Optimized Product Design













UNIQUE SELLING PROPOSITION



VALUE PROPOSITION

Improved patient compliance through

- a unique oral liquid formula that is easier to swallow compared to solid tablets and capsules
- superior patient adherence due to meticulously designed product making the reconstitution step easy and reliable

INNOVATIVE TECHNOLOGY

Our novel proprietary MMCR technology enables the delivery of esomeprazole

- under the form of coated microparticles suspended in a highly stable syrup
- overcoming the intrinsic acidlabile characteristics of any PPI.

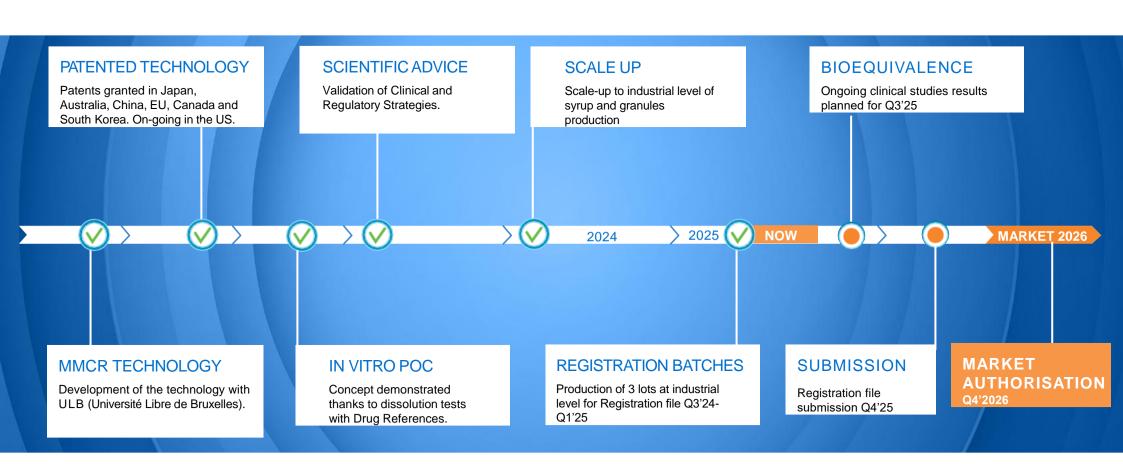
COMPETITIVE ADVANTAGES

Unlike most of the paediatric liquid products, SyrCeltTM Esomeprazole offers a unique combination of

- gastro-resistance formula without the undesirable effects of buffering and stabilizing agents
- flexible weight-based dosing depending on patient age
- long stability upon reconstitution that doesn't require preparation by a pharmacist

ROADMAP FOR THE 2027 LAUNCH OF SyrCelt™ ESOMEPRAZOLE IN EU MARKETS

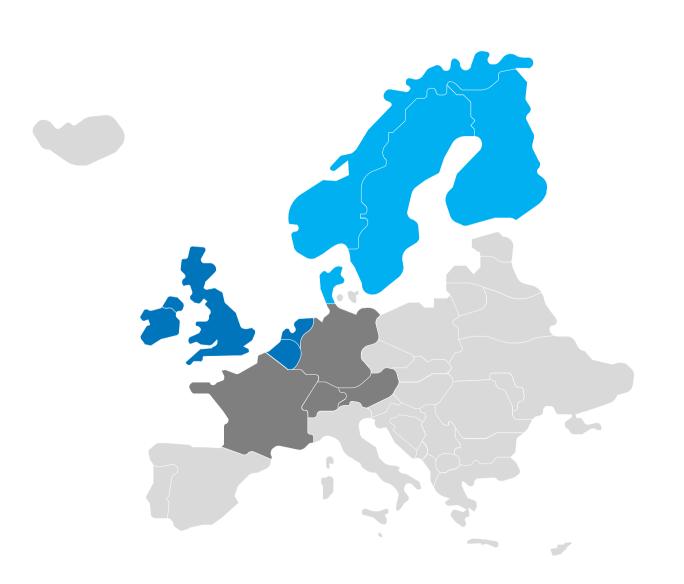




Note: Indicated dates are expected completion dates

CURRENT OUT LICENSING STATUS







Out licensed markets

The Netherlands
Belgium
Luxemburg
United Kingdom
Ireland



Markets prospected

Sweden Norway Denmark Finland



Scouting Markets

Germany/ Austria / Switzerland France



Interested?

We're seeking ambitious pharmaceutical collaborators to advance the development and commercialization our MMCR Esomeprazole Syrup.

If your portfolio includes gastroenterology or pediatric products—and you're looking to expand—we are keen to explore the out-licensing of this innovative solution.

Email us at dwy@bepharbel.com to arrange an introductory meeting.

We look forward to connecting!



BePharBel Manufacturing

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