

Designed for patients with swallowing difficulties or those who require administration via a nasogastric tube

Indications for Use:

# Chronic Heart Failure (CHF) with Reduced Systolic Left Ventricular Function:

- Bisoprolol is indicated for the treatment of stable chronic heart failure in patients with reduced systolic left ventricular function.
- It complements existing therapies such as ACE inhibitors, diuretics, and optionally cardiac glycosides.

#### Hypertension (High Blood Pressure):

 Additionally, it is effective in the treatment of hypertension (high blood pressure).

#### Angina (Chest Pain):

 It is also used for the management of angina, providing relief from chest pain associated with reduced blood flow to the heart.

Available strength: 2.5mg/5 ml (dosage in the range of 1.25 - 10mg can be administered)

## Benefit for the Target Population:

- The product containing Bisoprolol in the form of an oral liquid (solution) is specifically intended for patients with swallowing difficulties.
- It serves as a substitute for tablets, enhancing patient compliance.
- Additionally, it helps lower the pill burden for patients.

#### **Reference Markets:**

 Bisoprolol remains the largest beta-blocker, with approximately 2.0 billion tablets sold (MAT Q2 2022) according to IQVIA data for the EU27+UK. Ready-to-use solution for adult use

Allows for convenient dosing using an oral syringe

#### **Regulatory pathway**

• Legal basis: Article 10(3) hybrid application

## **Development status**

- Our clinical strategy includes assessing the bioequivalence of the solution vs. tablets, which has been confirmed through a successful bioequivalence study.
- The dossier submission is planned for May 2024.

# **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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