VALSARTAN LOW-DOSE (Supra Bioavailable) Tablets

Lower dose, equivalent absorption

- **Indicated for:**
  - Primary Hypertension: Used for the treatment of primary hypertension in adults.
  - Heart Failure: Reduces the risk of hospitalization in patients with heart failure.
  - Left Ventricular Dysfunction: Decreases the risk of cardiovascular death in patients with left ventricular dysfunction.

Minimized non-absorbed API in the gastrointestinal tract

Lower strengths equivalent to 40mg, 80mg, 160mg, 320mg of the reference product

Reduced environmental impact

Supra Bioavailability

- Valsartan in available formulations is absorbed with less than 20%.
- Our innovative formulation of Valsartan ensures supra-bioavailability, meaning it is absorbed more efficiently by the body compared to traditional formulations.
- This increased bioavailability reduces the amount of API wasted into the environment, minimizing its impact.

Environmental Benefits

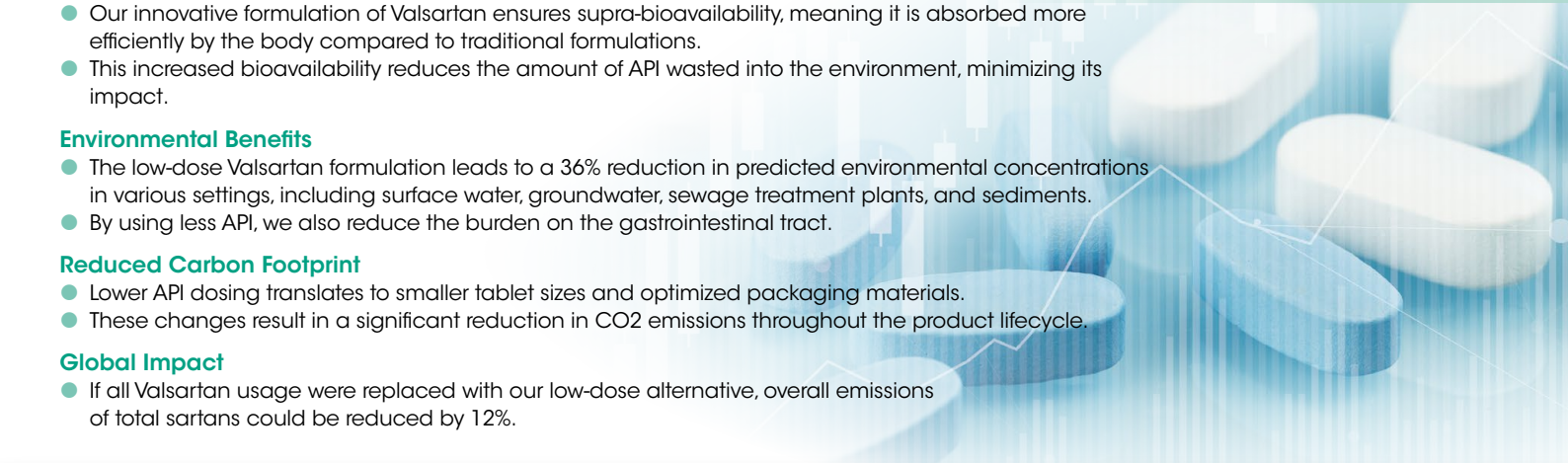
- The low-dose Valsartan formulation leads to a 36% reduction in predicted environmental concentrations in various settings, including surface water, groundwater, sewage treatment plants, and sediments.
- By using less API, we also reduce the burden on the gastrointestinal tract.

Reduced Carbon Footprint

- Lower API dosing translates to smaller tablet sizes and optimized packaging materials.
- These changes result in a significant reduction in CO_2 emissions throughout the product lifecycle.

Global Impact

- If all Valsartan usage were replaced with our low-dose alternative, overall emissions of total sartans could be reduced by 12%.



Regulatory pathway

- Reference medicinal product: Diovan, from Novartis
- Legal basis: Article 10(3) hybrid application
- Scientific adcivce planned Q4/2023

Development status

- A proof of concept clinical study has been conducted.
- Prototype development is in progress, and a pilot PK study is planned for Q3/2024.
- Our clinical strategy involves a dose-finding study, followed by a pivotal PK study scheduled for Q3/2025.
- The EU dossier is expected to be completed by 2026.

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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