



# CANDESARTAN LOW-DOSE (Supra Bioavailable) Tablets

Lower dose with the same level of absorption compared to higher standard dose

- **Indicated for:**

- Treatment of primary hypertension in adults
- Treatment of hypertension in children and adolescents aged 6 to <18 years
- The treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction  $\leq 40\%$ ) when Angiotensin Converting Enzyme (ACE)-inhibitors are not tolerated or as add-on therapy to ACE-inhibitors in patients with symptomatic heart failure, despite optimal therapy, when mineralocorticoid receptor antagonists are not tolerated

Less non-absorbed API in the gastrointestinal tract

Lower impact to environment

Lower strengths equivalent to 4mg, 8mg, 16mg, 32mg of the reference product

## Supra bioavailable – lower impact to environment

- Candesartan supra-bio-available with the same indication as Candesartan
- Candesartan in available formulations is absorbed with less than 20%, thereby a significant amount of API is wasted into the environment
- Lower API dosed with the same efficacy – hence less API as burden to the gastrointestinal tract, as well as being environmentally friendly

## Reference markets

- Candesartan market in EU27+UK is 549m€ and growing (MAT Q2 2022), as per IQVIA



## Regulatory pathway

- Legal basis: Article 10(3) hybrid application

## Development status

- Prototype development; pilot PK study planned
- Clinical Strategy: dose finding study followed by pivotal PK study
- EU dossier expected to be completed by 2026

## 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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