



S-AMLODIPINE (Levoamlodipine) Tablets

- **Indicated for** treatment of hypertension, chronic stable angina pectoris, vasospastic angina. These are same indications as Amlodipine, however with lower side effects (oedema)

Same efficacy as
Amlodipine with lower
occurrence of oedema

Oedema is
considered as the main
reason for treatment
discontinuation

Available strengths: 2.5mg, 5mg (equivalent to 5mg, 10mg Amlodipine)

Positive KOL feedback

Same efficacy as racemate with lower occurrence of oedema

- Oedema side effects can be seen in 10% of the patients, * taking 10mg dose
- Oedema is considered as the main reason for treatment discontinuation or leads to switch to less preferred treatments
- Published clinical data show a significantly lower incidence of oedema for S-Amlodipine vs. the racemate

Reference markets

- Amlodipine continues to be one of the main therapies for hypertension, with sales of 6.5b Tablets (MAT Q2 2022) and growing as per IQVIA

*Ref - Norvasc Leaflet - https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019787s047lbl.pdf

MAT - Moving Annual Total

Regulatory pathway

- Legal basis: Article 10(3) hybrid application

Development status

- Pre-formulation stage
- Clinical Strategy: PK studies versus racemate, safety study vs. rac-Amlodipine with oedema endpoints, scientific advice has been conducted in Oct 2022
- EU dossier expected to be completed by 2025

Partnership options

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

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