



# ROSUVASTATIN - all strengths including 15mg and 30mg Film-coated Tablets

- **Indicated for** treatment of primary hyperlipidemia and mixed dyslipidemia to reduce elevated total-C, LDL-C, ApoB, non-HDL-C, and TG, and to increase HDL-C

Dossier with 5, 10, 15, 20, 30, 40mg available for submission

## Cost competitive

- The product is based on standard technology and is produced in Europe

## Simplified set-up of the therapy

- Improved titration options for physicians. This is especially relevant to achieve target dose and consequent cholesterol levels, while avoiding side effects of this lifelong treatment

## Differentiation from competition

- Differentiation offering - standing out from competition

Complete scope of strengths, including 15mg and 30mg

Improved titration options for physicians

Low competition - 15mg and 30mg not available in all markets yet



## Regulatory pathway

- Dossier ready for submission
- Reference medicinal product: Crestor, film-coated tablets from AstraZeneca
- Legal basis: Article 10(1) generic application for 5/10/20/40 mg and Article 10(3) hybrid application for 15/30 mg


## Development status



- EU dossier approved

## Partnership options

- Product is available for out-licensing in Europe

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