March 2023

Public assessment summary report

Name of the Finished Pharmaceutical Product	Rosutrox, 5 mg, film coated tablets Rosutrox, 10 mg, film coated tablets Rosutrox, 20 mg, film coated tablets Rosutrox, 40 mg, film coated tablets
Manufacturer of the Finished Product	Biofarm Sp. z o.o. Poland 13 Wałbrzyska St. 60-198 Poznań – Poland
Active Pharmaceutical Ingredient (API)	Rosuvastain calcium

1. Introduction

Based on review of quality, safety and efficacy data through the abbreviated approval procedure, the authority granted a marketing authorization for Rosutrox 5 mg, 10 mg, 20 mg and 40 mg film coated tablets.

Rosutrox is indicated for the treatment of hypercholesterolaemia in adults, adolescents and children aged 6 years and older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non- pharamacological treatments.

2. Assessment of quality

GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product manufacturer has been carried out. Marketing authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

Stability testing:
It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia. The packaged product was stored at the long term condition of 30ºC/75% RH and at the accelerated condition of 40°C/75%RH.The packaging components used are the same as those for proposed commercial package for the marketed product. Based on the data presented, shelf life of 36 months was proposed.

3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit–risk profile of Rosutrox 5 mg, 10 mg, 20 mg and 40 mg film coated tablets are acceptable for the treatment indicated above.