COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Gabapentine Strides 800 mg, film-coated tablets

(gabapentin)

NL/H/4661/002/DC

Date: 14 September 2021

This module reflects the scientific discussion for the non-approval of Gabapentine Strides 800 mg, film-coated tablets. The procedure was finalised at 1 December 2019.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Gabapentine Strides 800 mg, film-coated tablets, from Strides Pharma (Cyprus) Limited.

The indications applied for concerns:

- Epilepsy
  Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.

- Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.

- Treatment of peripheral neuropathic pain
  Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

The concerned member states involved in this procedure were Germany, Spain, France and Sweden.

The marketing authorisation was applied pursuant to Article 10(1) of Directive 2001/83/EC.

Withdrawal of 600 mg strength
Initially, the application included an additional strength: Gabapentine Strides 600 mg, film-coated tablets. This strength has been withdrawn during the procedure and before finalisation.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to major objections qualifying as a potential serious risk to public health as defined in the Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC — March 2006 (2006/C 133/05).

Quality
The proposed production and quality control methods cannot guarantee that a major deficiency in the quality of the product will not occur. The dissolution stability values at 24 months are not sufficient to establish a shelf-life for Gabapentine Strides, in view of the ICH stability guidelines. The criteria for the study in the guidelines regarding study design should have been followed.

For establishing a product shelf-life, the stability studies should have also comprised adequate dissolution stability results of product batches with 30 minutes as dissolution measuring time point. The initial results (T0) should have been reported, and the results at interim storage times of the batches (according to the ICH stability guidelines) up to the end of the studies, depending on the claimed shelf-life.
Furthermore, the results of at least one more pilot batch or commercial scale batch should have been provided, stored long term during at least six months. Extrapolation of shelf-life based on the results was not considered not possible due to dissolution results of stored batches provided in the past which do no comply with the limit.

Therefore, the Board concluded that the marketing authorisation for Gabapentine Strides 800 mg, film-coated tablets cannot be granted. Agreement on this conclusion was reached with the Concerned Member States. The decentralised procedure was finalised with a negative outcome on 1 December 2019.