COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Hyoscine butylbromide RIA 10 mg, film-coated tablets (butylscopolamine bromide)

NL/H/5160/001/DC

Date: 14 April 2022

This module reflects the scientific discussion for the non-approval of Hyoscine butylbromide RIA 10 mg, film-coated tablets. The procedure was finalised at 22 February 2022.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Hyoscine butylbromide RIA 10 mg, film-coated tablets, from RIA Generics Limited.

The indications applied for concerns:

Hyoscine butylbromide RIA are indicated for the relief of spasm of the genito-urinary tract or gastro- intestinal tract and for the symptomatic relief of Irritable Bowel Syndrome.

The concerned member state (CMS) involved in this procedure was Malta.

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

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted as no conclusion on bioequivalence under fasted conditions could be drawn between Hyoscine butylbromide RIA 10 mg, film-coated tablets and the reference product Buscopan, uberzogene Tabletten 10 mg. this was due to several deficiencies in the study documentation which will be discussed below.

Clinical

Deficiencies in the study documentation of the bioequivalence study consisted of the following:

- The approval letter from the ethical committee that was provided by the applicant concerned a different study than was submitted.
- In accepted bioanalytical runs, quality control samples that were outside the acceptance criteria were excluded to obtain accuracy and precision values which were within the acceptance range. This is not in line with the requirements of the bioanalytical guideline.
- Incomplete data analysis details were submitted, a certain amount of analyses were repeated, but a different amount was listed.
- Concentration-time curves were not clear, and data points were depicted in figures which did not match the sampling schedule.

Therefore, the Board concluded that the marketing authorisation for Hyoscine butylbromide RIA 10 mg, film-coated tablets cannot be granted. Agreement on this conclusion was reached with the CMS. The decentralised procedure was finalised with a negative outcome on 24 February 2022.