COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Veroxol mint 20 mg, lozenges

(ambroxol)

NL/H/3673/001/DC

Date: 7 September 2018

This module reflects the scientific discussion for the non-approval of Veroxol mint 20 mg, lozenges. The procedure was finalised at 29 May 2017.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Veroxol mint 20 mg, lozenges from Geiser Pharma.

Veroxol is a local anaesthetic used for pain relief of mild to moderate symptoms of acute sore throat.

The marketing authorisation was applied pursuant to Article 10(3) of Directive 2001/83/EC, a hybrid application as for locally acting medicinal products such as lozenges bioequivalence cannot be demonstrated through bioavailability studies.

The concerned member states in this procedure were Germany, France, Poland and Portugal.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted as the equivalence between the proposed Veroxol mint 20 mg, lozenges and the reference product Mucoangin 20 mg lozenges has not been demonstrated by the submitted in vivo release study.

Pharmacokinetics

Veroxol lozenges is a locally applied locally acting product. Therefore, demonstration of equivalent availability at the site of action can be considered as a surrogate of therapeutic equivalence for efficacy whereas equivalent systemic exposure supports safety. To support the claim of therapeutic equivalence the MAH submitted two comparative studies: one in vivo release study to support equivalent local availability at site of action and a comparative bioavailability study. The type of studies, assessment of the local availability indirectly by the amount remaining in the dosage form at selected time points as well as the comparative bioavailability study was considered acceptable.

However, equivalence between the proposed Veroxol 20 mg lozenges and Mucoangin 20 mg lozenges could not be concluded since dissolution profile similarity based on an acceptance range of ±10% in accordance to the acceptance range (≥50) of the f2 similarity factor has not been demonstrated.

Therefore, the Board concluded that the marketing authorisation for Veroxol mint 20 mg, lozenges cannot be granted. Agreement on this conclusion was reached with the Concerned Member States. The decentralised procedure was finalised with a negative outcome on 29 May 2017.