COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Lidocata 700 mg medicated plaster

(lidocaine)

NL/H/5218/001/DC

Date: 20 September 2023

This module reflects the scientific discussion for the non-approval of Lidocata 700 mg medicated plaster. The procedure was finalised at 5 July 2023.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Lidocata 700 mg medicated plaster, from Wooshin Lapache d.o.o.

The indications applied for was the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults.

The applicant was claiming equivalence to the innovator product Versatis 700 mg medicated plaster which has been registered in Germany by Grünenthal Limited since 29 January 2014. In the Netherlands, Versatis has been registered via a mutual recognition procedure (DE/H/5733/001/MR).

The concerned member states (CMS) involved in this procedure were France, Germany, Italy and Spain.

The marketing authorisation was applied for pursuant to Article 10(3) of Directive 2001/83/EC, a hybrid application.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to major objections qualifying as 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).

Pharmacokinetics

The applicant has not demonstrated that the differences between the test and the reference product in excipients, adhesion and lidocaine skin permeation do not lead to inferior local tolerability of the test product versus the reference product.

The study performed by the applicant was not in line with the EMA guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms and not considered adequate to reliably quantify cumulative irritation potential of the test product in comparison to the reference product. Therefore, similarity of the irritation potential between the test and the reference product has not been established.

In the Board meeting of 29 June 2023, the above issue was discussed.

Therefore, the Board concluded that the marketing authorisation for Lidocata 700 mg medicated plaster cannot be granted. Agreement on this conclusion was reached with the concerned member states. The decentralised procedure was finalised with a negative outcome on 5 July 2023.