

Public Assessment Report

Scientific discussion

**Suxamethonium Accord 50 mg/ml solution
for injection/infusion in pre-filled syringe**

(suxamethonium chloride)

NL/H/4767/001/DC

Date: 16 September 2020

This module reflects the scientific discussion for the non-approval of Suxamethonium Accord 50 mg/ml solution for injection/infusion in pre-filled syringe. The procedure was finalised at 2 July 2020.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Suxamethonium Accord 50 mg/ml solution for injection/infusion in pre-filled syringe, from Accord Healthcare B.V.

The indication applied for concerns:

Suxamethonium an ultra-short acting, depolarising, neuromuscular blocking agent for producing muscular relaxation during anaesthesia. It is used in anaesthesia as a muscle relaxant to facilitate endotracheal intubation, mechanical ventilation and a wide range of surgical and obstetric procedures.

It is also used to reduce the intensity of muscle contractions associated with Pharmacologically or electrically-induced convulsions

The marketing authorisation was applied pursuant to Article 10(3) of Directive 2001/83/EC, a hybrid application. The European reference product was Anectine 50 mg/mL solution for injection or infusion (Aspen Pharma Trading Limited, Ireland), which was authorised in Ireland nationally on 1 April 1979.

The concerned member states in this procedure were Austria, Belgium, Czech Republic, Finland, France, Germany, Ireland, Norway, Poland, Portugal, Romania, Spain and Sweden.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to 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 sterility of the empty syringes and the sterility and quality of the drug product could not be established, since:

- Pivotal quality data related to the proposed terminal sterilisation process was not available, no assessment and hence no conclusion could be made with regard to quality including sterility of the drug product.
- The initial decrease in pH after manufacturing and without or prior to sterilisation was not sufficiently clarified.
- The ethylene oxide sterilisation of the empty syringes was not adequately validated.

Therefore, the Board concluded that the marketing authorisation for Suxamethonium Accord 50 mg/ml solution for injection/infusion in pre-filled syringe cannot be granted. Agreement on this conclusion was reached with the concerned member states. The

decentralised procedure was finalised with a negative outcome on 2 July 2020.