LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Omnicol
(sodium hydrogen carbonate, potassium chloride, sodium chloride, macrogol)

SE/H/2697/001/MR

This module reflects the scientific discussion for the approval of Omnicol. The procedure was finalised at 2025-09-30. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have agreed to grant a marketing authorisation for Omnicol, Powder for oral solution in sachet.

The active substance is sodium hydrogen carbonate, potassium chloride, sodium chloride, macrogol. A comprehensive description of the indication and posology is given in the SmPC.

II. EXECUTIVE SUMMARY

This is a hybrid application for a formulation of Omnicol powder for oral solution, sachet under Article 10 (3) of Directive 2001/83/EC. The applicant, Pro Health Pharma Sweden AB applies through the mutual recognition procedure.

The original product in Sweden is Movicol, powder for oral solution, sachet, marketed by Norgine BV, Netherlands.

The product contains the drug substances Macrogol 3350 (13,125 g), sodium chloride (351 mg), sodium hydrogen carbonate (178 mg) and potassium chloride (47.0 mg) and is indicated for the treatment of chronic constipation. The sachets contain 13.8 g powder to be dissolved in 125 ml water before administration to the patient.

III. SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 Quality aspects

Drug substance
The structure of the drug substance has been adequately proven, and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described, and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

Drug Product
The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III.2 Non-clinical aspects

The pharmacodynamic, pharmacokinetic and toxicological properties of Macrogol 3350 are considered well known. As Macrogol 3350 is a widely used, well-known active substance no further studies are required and the applicant provides none. An overview based on literature review is appropriate. There are no additional comments on the nonclinical dossier or on the SPC.
Since Omnicol is a generic macrogol 3350-containing product the use of Omnicol is not considered to increase the risk to the environment beyond or above that which may be caused by other macrogol-containing products.

III.3 Clinical aspects

III.3.1 Pharmacokinetics

A bioequivalence study has not been performed since this is not necessary when the product is to be administered as an aqueous oral solution containing the same active substance in the same concentration as the currently authorised product. Furthermore, macrogol 3350 is not absorbed from the gastrointestinal tract and is unchanged along the gut.

III.3.2 Pharmacodynamics

The high molecular weight macrogols act by retaining water molecules. The increased volume of intestinal fluids accounts for the laxative effect of the solution.

III.3.3 Clinical efficacy

No new efficacy data have been submitted or are required.

III.3.4 Clinical safety

No new safety data have been submitted or are required.

III.3.5 Pharmacovigilance system

Provided that the deficiency is rectified prior to the applicant placing the medicinal product on the market, the MPA may consider that the Pharmacovigilance system will fulfil the requirements. The applicant must ensure that the system of pharmacovigilance is in place and functioning before the product is placed on the market.

III.3.6 Risk Management Plan

The MAH has submitted an updated risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Omnicol and Omnicol Junior. Risks initially listed as important have been re-classified, to align with the removal of safety concerns during the initial MPA assessment and with the HaRP assessment report of 15 July 2019.

Safety specification

Table SVIII.1: Summary of safety concerns

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

Pharmacovigilance Plan

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures

Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Summary of the RMP

The submitted Risk Management Plan, version 1.2 is considered acceptable.

III.3.7 Periodic Safety Update Report (PSUR)

Active substance is currently listed in the published EURD list.

With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.

- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.

In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.

IV. BENEFIT RISK ASSESSMENT

The benefit/risk ratio is considered to be similar for Omnicol powder for oral solution, sachet and Movicol, powder for oral solution, sachet, (Norgine BV) and hence favourable.

V. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

V.1 List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

N/A

V.2 List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

N/A

V.3 Summary of Product Characteristics (SmPC)

The approved SmPC is available in the MRI Product Index.

V.4 Package Leaflet (PL)

V.4.1 Package Leaflet

The approved PL is available in the MRI Product Index.

V.4.2 Assessment of User Testing

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PL was Swedish. Assessment of the User Testing is attached in Appendix I.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

V.5 Labelling

The approved Labelling is available in the MRI Product Index.

VI. STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
-	-	-	-	-	-