LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral
(sodium hydrogen carbonate, sodium chloride, potassium chloride, macrogol)

SE/H/2559/01-03/DC

This module reflects the scientific discussion for the approval of Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral. The procedure was finalised on 2025-05-14. 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

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral, Powder for oral solution in sachet.

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

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

The application for Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral, Powder for oral solution, is a Hybrid Art. 10(3) application submitted according to Directive 2001/83/EC. The applicant applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and NO, DK, PL as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Movicol, Powder for oral solution in sachet authorised in SE since 1996, with Norgine Healthcare B.V. as marketing authorisation holder.

European Reference Product (ERP)
A European Reference Product is used in CMS:
NO and PL: Movicol Neutral
PL: Movicol and Movicol Junior Neutral, Powder for oral solution in sachet authorised in SE since 1996, with Norgine Healthcare B.V. as marketing authorisation holder.
The justification to use this product is based on RMS's own files. The ERP information was circulated during the validation period.

Potential similarity with orphan medicinal products

N/A

II. QUALITY ASPECTS

II.1 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.

II.2 Medicinal 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. NON-CLINICAL ASPECTS

Pharmacodynamic, pharmacokinetic and toxicological properties of macrogol 3350 are well known. As macrogol 3350 is a widely used, well-known active substance, no further studies are required, nor does the applicant provide any. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)
Since Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral is a generic product, it will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

There are no objections to approval of Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral from a non-clinical point of view.

IV. CLINICAL ASPECTS

Pharmacokinetics
According to the Guideline on the investigation of Bioequivalence (CHMP/QWP/EWP/1401/98 Rev. 1) and the Guideline on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied, locally acting in the gastrointestinal tract CPMP/EWP/239/95 Rev. 1, Corr.1, bioequivalence studies may be waived if the test product is an aqueous oral solution at time of administration and contains an active substance in the same concentration as an approved oral solution. However, if the excipients may affect gastrointestinal transit, absorption, solubility or stability, a bioequivalence study should be conducted, unless the differences in the amounts of these excipients can be adequately justified by reference to other data.

Discussion and overall conclusion
The applied for product is an aqueous oral solution containing the same active substances in the same concentration as the currently authorised product and the excipients are both qualitatively and quantitatively similar. Furthermore, macrogol 3350 is not absorbed from the gastrointestinal tract and is unchanged along the gut.

Waiving bioequivalence studies is acceptable.

Pharmacodynamics/Clinical efficacy/Clinical safety
No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted. Provided that bioequivalence with the originator product is demonstrated, or a biowaiver is accepted, additional data is not necessary.
An overview of literature data up to February 2024 has been provided as supportive data.

Risk Management Plan

The MAH has submitted a 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 Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral.

Part II Safety specification

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

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

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

Part VI Summary of the RMP
The Summary of the RMP is endorsed.

Conclusion RMP assessment
The submitted Risk Management Plan, version 1.0 signed 18.10.2024 is considered acceptable.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. USER CONSULTATION

A user consultation with target patient groups on the package information leaflet (PL) has been performed on the basis of a bridging report making reference to Movicol Junior Neutral sachet, powder for oral solution (SE/H/1799/03) for content and Kaliumklorid Orifarm 750 mg prolonged release tablets (DK/H/2347/001) for layout.

The bridging was assessed and accepted at day 70.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral, is found adequate. There are no objections to approval of Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral, from a non-clinical and clinical point of view. The absence of bioequivalence studies is acceptable. The product information is acceptable. The benefit/risk is considered positive, and the application is therefore recommended for approval.

List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

The decentralised procedure for Abdomin Neutral, Abdomin Citrus, Abdomin Junior Neutral, Powder for oral solution in sachet was positively finalised on 2025-05-14.

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Public Assessment Report – Update

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

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
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Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se