LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Pamol Novum
(paracetamol)

SE/H/2567/01/DC

This module reflects the scientific discussion for the approval of Pamol Novum. The procedure was finalised on 2025-08-06. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Pamol Novum, 500 mg, film-coated tablet.

The active substance is paracetamol. 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 Pamol Novum, 500 mg, film-coated tablet, is a generic art. 10(1) 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 and DK as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Panodil Zapp, 500 mg, film-coated tablet authorised in DK since 2000, with Haleon Denmark ApS as marketing authorisation holder.

The reference product used in the in vitro study for BCS biowaiver is Panodil Zapp, 500 mg, film-coated tablet from DK with name of Haleon Denmark ApS as marketing authorisation holder.

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

Pharmacology/Pharmacokinetics/Toxicology
Pharmacodynamic, pharmacokinetic and toxicological properties of paracetamol are well known. As paracetamol 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 Pamol Novum 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 Pamol Novum from a non-clinical point of view.

IV. CLINICAL ASPECTS

Pharmacokinetics

Pharmacokinetic properties of the active substance

Absorption: Following oral administration, paracetamol is readily absorbed and the maximal plasma concentrations occur at approximately 30 minutes after ingestion irrespective of food intake.

Elimination: The terminal plasma half-life is approximately 2 hours.

BCS-based biowaiver

The application is based on a Biopharmaceutical Classification System (BCS) based biowaiver and no bioequivalence study has been submitted. The applicant claims that paracetamol (acetaminophen) belongs to BCS-class I and that bioequivalence studies can be waived.

According to the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr) and ICHM9, a BCS class I-based biowaiver is applicable for an immediate release product if the drug substance is not considered to have a narrow therapeutic index and has been proven to exhibit high solubility and complete absorption/high permeability (BCS class I). Also, in-vitro dissolution characteristics of the test and the reference product should be either very rapid or similarly rapid and the excipients that might affect bioavailability should be quantitatively and qualitatively the same.

Discussion and overall conclusion

The justification for BCS (Biopharmaceutics Classification System) based biowaiver can be accepted from a pharmacokinetic perspective. It can be concluded that the drug substance has been proven to exhibit high solubility and complete absorption (BCS class I). According to EMA/CHMP/356877/2017 Rev.1 *Paracetamol oral use immediate release formulations product-specific bioequivalence guidance* the active substance, paracetamol, is classified as a BCS class I substance with high solubility and complete absorption. Paracetamol is not considered to have a narrow therapeutic index in the sense that narrowed acceptance ranges would be necessary in bioequivalence studies performed with paracetamol. None of the excipients included in the drug

product are known to influence bioavailability. The difference in excipients is acceptable for a BCS class I-biowaiver. The quality criteria regarding dissolution have also been fulfilled.

In conclusion, the justification for a BCS (Biopharmaceutics Classification System) based biowaiver can be accepted.

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, additional data is not necessary.

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 Pamol Novum.

Part II Safety specification
The MAH has submitted the version 1.0 RMP dated 2024-04-04 and proposed the following 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 2024-04-04 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 Paracetamol Bluefish PT/H/2644/001/DC for content and Kaliumklorid Orifarm DK/H/2347/001 for layout.

The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Pamol Novum, is found adequate. There are no objections to approval of Pamol Novum, from a non-clinical and clinical point of view. The absence of bioequivalence studies is acceptable since the BCS-based biowaiver 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 Pamol Novum, 500 mg, film-coated tablet was positively finalised on 2025-08-06.

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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)

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