IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Panadol 500 mg soluble tablets
Paracetamol
PA0678/039/017

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Panadol 500 mg Soluble Tablets, from GlaxoSmithKline Consumer Healthcare (Ireland) Limited.

Indications
As a mild analgesic and antipyretic. The tablets are recommended for use in the short-term management of the symptoms of headache, toothache, menstrual pain, musculoskeletal disorders and for symptoms of common colds and 'flu including sore throat, headache, muscle ache and fever. Panadol may also be used in the symptomatic relief of mild to moderate pain associated with osteoarthritis, as diagnosed by a doctor.

This application for a marketing authorisation was submitted in accordance with Article 10c of Directive 2001/83/EC and is referred to as an 'informed consent' application. This means that the Marketing Authorisation Holder for Panadol ActiFast 500 mg Soluble Tablets (PA0678/039/013), an authorised medicinal product in Europe (Ireland), has permitted the applicant to refer to their dossier to obtain an authorisation for Panadol 500mg Soluble Tablets. Panadol 500 mg Soluble Tablets has the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Panadol ActiFast 500 mg Soluble Tablets.

Prescription status
General sale with a maximum pack size of 12 tablets. Product supplied in blister packs. Maximum one pack per sale.

Retail sale through pharmacies only with a maximum pack size of 24 tablets. Product supplied in blister packs. Maximum two pack per sale.

Prescription only for any pack size exceeding 24 tablets. Product not supplied in blister packs.

The Summary of Product Characteristics for (SmPC) for this medicinal product is available on the HPRA's website at www.hpra.ie.

Name of the product	Panadol 500 mg Soluble Tablets
Name(s) of the active substance(s) (INN)	Paracetamol
Pharmacotherapeutic classification (ATC code)	Paracetamol-N02BE01
Pharmaceutical form and strength(s)	Soluble tablet, 500 milligrams
Marketing Authorisation Number(s) in Ireland (PA)	PA0678/039/017
Marketing Authorisation Holder	GlaxoSmithKline Consumer Healthcare (Ireland) Limited
New National Case No.	CRN009TF5

II. QUALITY ASPECTS

II.1. Introduction

This application is for Panadol 500 mg soluble tablets.

II.2 Drug substance

The active substance is Paracetamol, an established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided under the dossier of Panadol ActiFast 500 mg soluble tablets.

II.3 Medicinal product

P.1 Composition

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines as provided for under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated as provided for under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications as provided for under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for the dosage form, and the tests and control limits are considered appropriate for this type of product based on the reference to the dossier of Panadol ActiFast 500mg Soluble Tablets.

The analytical methods used are described in sufficient detail and are supported by validation data as provided for under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

Batch analytical data for a number of batches from the proposed production site(s) have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality as provided for under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

P.7 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging complies with Ph. Eur./EU legislation for use with foodstuffs requirements as provided for under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

P.8 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines under the dossier of Panadol ActiFast 500 mg Soluble Tablets and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Panadol 500 mg soluble tablets, under the dossier of Panadol ActiFast 500 mg Soluble Tablets.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is the same as that present in Panadol ActiFast 500mg Soluble Tablets on the European market. No new preclinical data have been submitted. As such, no pre-clinical assessment has been made on the application. This is acceptable for this type of application.

III.5 Ecotoxicity/environmental risk assessment

Since Panadol 500 mg Soluble Tablets is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

III.6 Discussion on the non-clinical aspects

As this is an informed consent application and paracetamol is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. The product information SmPC and patient leaflets are identical to those of the reference product.

IV. CLINICAL ASPECTS

IV.1 Introduction

Paracetamol is a well-known active substance with established efficacy and tolerability. This medicinal product is the same as Panadol ActiFast 500mg Soluble Tablets on the European market.

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product Panadol ActiFast 500mg Soluble Tablets (PA0678/039/014) marketed by GlaxoSmithKline Consumer Healthcare (Ireland) Limited.

IV.2 Pharmacokinetics

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Concentration in plasma reaches a peak in 30-60 minutes. Plasma half-life is 1-4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma protein binding is variable. Excretion is almost exclusively renal, in the form of conjugated metabolites.

IV.3 Pharmacodynamics

Paracetamol has analgesic and antipyretic actions.

IV.4 Clinical Efficacy

As this is an informed consent application no new clinical efficacy data has been submitted. Efficacy and safety is expected to be similar to the reference product Panadol ActiFast 500mg Soluble Tablets.

IV.5 Clinical Safety

As this is an informed consent application no new clinical safety data has been submitted. Efficacy and safety is expected to be similar to the reference product Panadol ActiFast 500mg Soluble Tablets.

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 Panadol 500 mg Soluble Tablets. Routine pharmacovigilance activities and routine risk minimisation measures are considered sufficient.

Periodic Safety Update Report (PSUR)
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.6 Discussion on the clinical aspects

Paracetamol is a well-known substance and has been widely marketed. As this is an informed consent application no new efficacy or safety data have been submitted. Efficacy and safety is expected to be similar to the reference product Panadol ActiFast 500mg Soluble Tablets.

The product information SmPC and patient leaflets are in line with those of the reference product.

V. OVERALL CONCLUSIONS

Panadol 500 mg Soluble Tablets is the same as Panadol ActiFast 500 mg Soluble Tablets. Panadol ActiFast 500 mg Soluble Tablets is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The HPRA, on the basis of the data submitted considered that Panadol 500 mg Soluble Tablets was the same as the reference product and therefore granted a marketing authorisation.

VII. UPDATES

This section reflects the significant changes following finalisation of the initial procedure.

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
New National	N/A	SmPC Sections 1 to 9	21st October 2022	20th October 2027