Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Paracetamol Plus 500mg/65mg Effervescent Tablets

paracetamol, caffeine

PL 16028/0183

Galpharm Healthcare Limited

LAY SUMMARY

Paracetamol Plus 500mg/65mg Effervescent Tablets
paracetamol, caffeine

This is a summary of the Public Assessment Report (PAR) for Paracetamol Plus 500mg/65mg Effervescent Tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Paracetamol and Caffeine Tablets in this lay summary for ease of reading.

For practical information about using Paracetamol and Caffeine Tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Paracetamol and Caffeine Tablets and what is it/they used for?
This application is the same as Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets (PL 02855/0079), which is already authorised.

The Company responsible for Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets, has agreed that its scientific data can be used as the basis for the grant of an identical licence/licences for Paracetamol and Caffeine Tablets.

Paracetamol and Caffeine Tablets can provide effective relief from headache and migraine. They can also relieve backache, rheumatic pain, toothache, sore throat, period pain and the fever, aches and pains of colds and flu.

How does Paracetamol and Caffeine Tablets work?
The tablets contain two active ingredients. Paracetamol is a painkiller and also reduces a person's temperature when they have a fever. Caffeine acts to further help the effectiveness of paracetamol.

How is Paracetamol and Caffeine Tablets used?
The pharmaceutical form of this medicine is tablets and the route of administration is by mouth (oral).

Adults and children aged 16 years and over:
Take 2 tablets dissolved in a tumbler of water, every 4-6 hours as needed.
- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets in 24 hours.

Children aged 12 – 15 years:
Take 1 tablet dissolved in a tumbler of water, every 4-6 hours as needed.
- Do not take more frequently than every 4 hours.
- Do not take more than 4 tablets in 24 hours.
- Do not take more than the recommended dose.
- Do not give to children under 12 years.
- Avoid too much caffeine in drinks like coffee and tea.

High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.

For further information on how Paracetamol and Caffeine Tablets is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can be obtained without a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Paracetamol and Caffeine Tablets have been shown in studies?
Paracetamol and Caffeine Tablets is considered identical to the previously authorised product/products with the same benefits and risks. |No new studies have been provided for Paracetamol and Caffeine Tablets, however, reference is made to the studies for Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets.

What are the possible side effects of Paracetamol and Caffeine Tablets?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.ukor search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Paracetamol and Caffeine Tablets is considered to be identical to the previously authorised product with the same benefits and risks.

Why was Paracetamol and Caffeine Tablets approved?
The MHRA decided that the benefits of Paracetamol and Caffeine Tablets are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Paracetamol and Caffeine Tablets?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Paracetamol and Caffeine Tablets The RMP details the important risks of Paracetamol and Caffeine Tablets, how these risks can be minimised, any uncertainties about Paracetamol and Caffeine Tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Paracetamol and Caffeine Tablets:

Summary of safety concerns	
Important identified risks	Hepatotoxicity at therapeutic doses (paracetamol)
Important potential risks	None.
Missing information	None.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Paracetamol and Caffeine Tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Paracetamol and Caffeine Tablets
A marketing authorisation was granted in the United Kingdom on 1 March 2023.

The full PAR for Paracetamol and Caffeine Tablets follows this summary.
This summary was last updated in October 2023.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Paracetamol Plus 500mg/65mg Effervescent Tablets (PL 16028/0183) could be approved.

The product is approved for the following indications:

For the treatment of most painful and febrile conditions, for example, headache including migraine, backache, toothache, colds and influenza, sore throat, rheumatic pain and dysmenorrhoea.

The combination of paracetamol and caffeine is a well established analgesic combination.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets.

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A national marketing authorisation was granted in the United Kingdom on 01 March 2023

II. EXPERT REPORT

The applicant cross-refers to the data for Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets, (Omega Pharma Limited), to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with that for Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets, dated 07/2022.

PATIENT INFORMATION LEAFLET

A mock-up has been provided which has been aligned with that for Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets, dated for 05/2022. The user test report submitted for PL 02855/0079 has been provided.

LABEL

Label mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specifications

The sources of the active substances are in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Product

Name

The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes

Paracetamol Plus 500mg/65mg Effervescent Tablets are available in Paper/PE/aluminium/PE laminate blister strips placed in cardboard carton outers containing 4, 6, 12, 16, 18, 24 or 30 tablets

The appearance of the product is identical to that of the cross-reference product.

The proposed shelf life of the product is 48 months with the recommended storage condition 'Do not store above 30°C'.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status

General Sales List (GSL) medicine.

Manufacturers

The proposed manufacturing sites are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions

The composition of the proposed product is consistent with the details registered for the cross-reference product.

Manufacturing process & control of critical steps

The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

Finished product release/shelf life specifications

The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference product.

TSE Compliance

No excipients of animal or human origin are used in the final products.

This product does not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Solpadeine Headache Soluble Tablets or SolpaPain 500mg/65mg Effervescent Tablets, PL 02855/0079, currently held by Omega Pharma Limited.

The bridging report submitted by the applicant is acceptable.

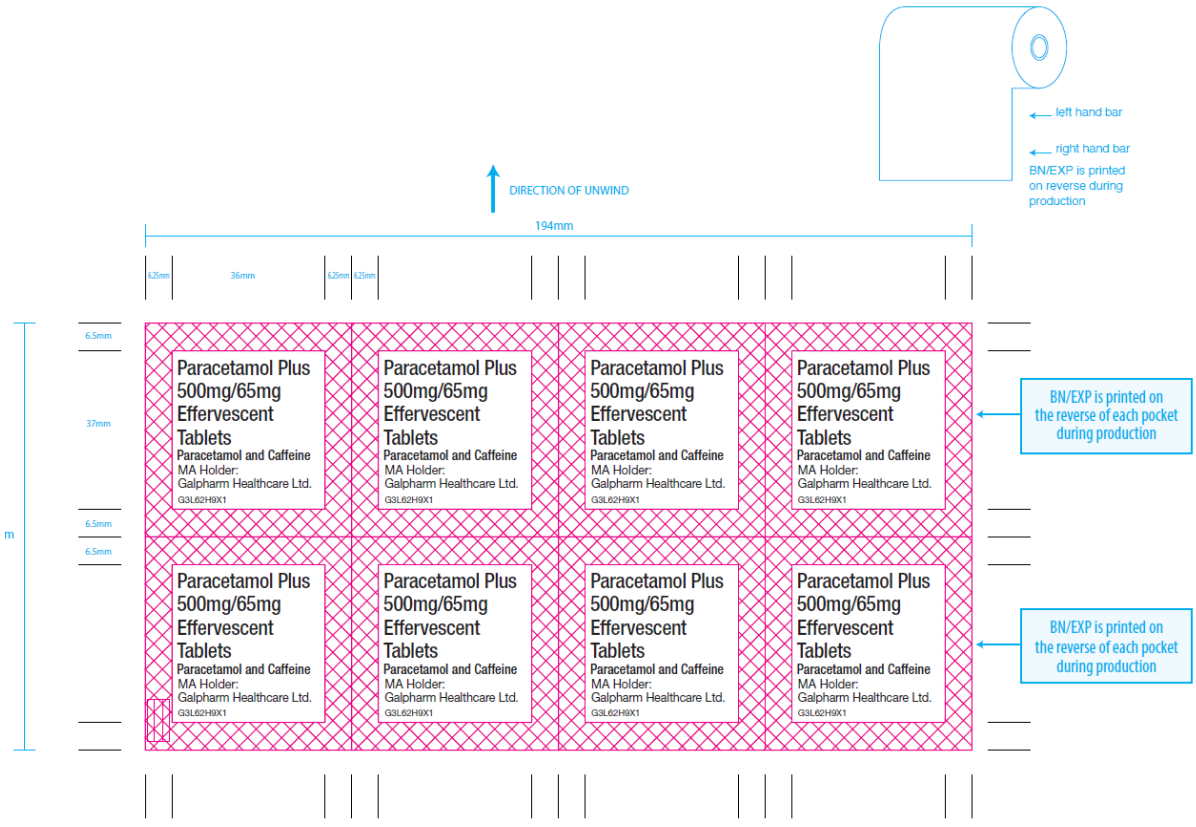
IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

Representative copies of the labels at the time of licensing are provided below.



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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**