



Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Paracetamol 500 mg Capsules

paracetamol

PL 44041/0194-0196

NOUMED LIFE SCIENCES LIMITED

LAY SUMMARY

Paracetamol 500 mg Capsules paracetamol

This is a summary of the Public Assessment Report (PAR) for Paracetamol 500 mg Capsules. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

For practical information about using Paracetamol 500 mg Capsules, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Paracetamol 500 mg Capsules and what are they used for?

These applications are the same as Paracetamol Capsules 500 mg (PL 44041/0165-0167) which already authorised.

The Company responsible for Paracetamol Capsules 500 mg has agreed that its scientific data can be used as the basis for the grant of an identical licences for Paracetamol 500mg Capsules.

Paracetamol 500 mg Capsules is used in the treatment of:

- joint pain, muscle pain.
- backache, toothache.
- nerve pain, period pain.
- headaches (including migraine, tension headache).
- sore throat.

It is also used to lower a high temperature and relieve the symptoms of cold and flu.

How do Paracetamol 500 mg Capsules work?

Paracetamol 500 mg capsules contain the active ingredient paracetamol. It belongs to a group of medicines called analgesics, which relieves pain and the symptoms of cold and flu.

How are Paracetamol 500 mg Capsules used?

The pharmaceutical form of these medicines is capsules, and the route of administration is oral (by mouth).

Adults, the elderly and children over 16 years:

- The usual dose of paracetamol is 2 capsules
- the capsules should be swallow whole with a drink of water
- the patient should wait at least 4 hours before taking another dose
- Do not take more than 4 doses in any 24-hour period

Children 10 -15 years of age:

Take One capsule every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children under 10

This medicine is **not recommended for children under 10 years of age.**

For further information on how Paracetamol 500 mg Capsules are used, refer to the PIL and Summaries of Product Characteristics (SmPC(s)) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription or 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 500 mg Capsules have been shown in studies?

Paracetamol 500 mg Capsules are considered identical to the previously authorised products with the same benefits and risks. No new studies have been provided for Paracetamol 500 mg Capsules.

What are the possible side effects of Paracetamol 500 mg Capsules?

For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPC(s) 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.uk> or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Paracetamol 500 mg Capsules are considered to be identical to the previously authorised products with the same benefits and risks.

Why were Paracetamol 500 mg Capsules approved?

The MHRA decided that the benefits of Paracetamol 500 mg Capsules are greater than the risks and recommended that these medicines are approved for use.

What measures are being taken to ensure the safe and effective use of Paracetamol 500 mg Capsules?

As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Paracetamol 500 mg Capsules. The RMP details the important risks of Paracetamol 500 mg Capsules, how these risks can be minimised, any uncertainties about Paracetamol 500 mg Capsules (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Paracetamol 500 mg Capsules:

Summary of safety concerns	
Important identified risks	<ol style="list-style-type: none"> 1. Hypersensitivity to paracetamol and/or other constituents. 2. Administration of paracetamol to patients with severe renal/severe hepatic impairment. 3. Hazards of overdose are greater in those with alcoholic liver disease. 4. Drowsiness, impairment of mental function and methaemoglobinaemia
Important potential risks	<ol style="list-style-type: none"> 1. Anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding.
Missing information	<ol style="list-style-type: none"> 1. Use in children under 12 years of age.

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

Other information about Paracetamol 500 mg Capsules

Marketing Authorisations were granted in the UK on 27 June 2025.

The full PAR for Paracetamol 500 mg Capsules follows this summary.

This summary was last updated in July 2025.

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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 applications for Paracetamol 500 mg Capsules PL 44041/0194-0196, could be approved.

The products are approved for the following indications:

Paracetamol capsules are recommended for the treatment of rheumatic and muscle pains, backache, nerve pains, headache including migraine and tension headaches, toothache, period pains, dysmenorrhoea, sore throat and for relieving the fever, aches and pains of colds and flu.

The name of the active substance is paracetamol which belongs to the pharmacotherapeutic group of other analgesics and antipyretics.

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependent on the inhibition of prostaglandin synthesis. The inhibition appears, however, to be on a selective basis.

These applications are national abridged applications approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as informed consent applications. The applications cross- refer to the reference products Paracetamol Capsules 500mg (PL44041/01650167).

No new non-clinical or clinical data have been supplied, and none are required for these informed consent applications.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions of already authorised products, 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 these products at all sites responsible for the manufacture, assembly and batch release of these products.

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

National marketing authorisations were granted in the UK on 27 June 2025.

II. EXPERT REPORT

The applicant cross-refers to the data for Paracetamol Capsules 500 mg (PL 44041/0165-0167), to which these applications are claimed to be identical. This is acceptable.

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

The SmPCs are in line with those for Paracetamol Capsules 500 mg (PL 44041/0165-0167).

PATIENT INFORMATION LEAFLET

The leaflet text and mock-up have been provided which have been aligned with that for Paracetamol 500 mg Capsules of cross-reference products (PL 44041/0165-0167), dated PL 44041/0165-June 2025, PL 44041/0166-April 2025 and PL 44041/0167- April 2025.

LABEL

Label text and/or mock-ups have been provided.

IV. QUALITY ASPECTS**IV.1 Drug Substance****Drug substance specification(s)**

The source of the active substance is in line with the cross-reference products. The proposed drug substance specification is consistent with the details registered for the cross-reference products.

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 500 mg Capsules PL 44041/0194 are to be available in PVC blister in pack sizes of 60, 84, 96, and 100.

Paracetamol 500 mg Capsules PL 44041/0195 are to be available in PVC blister in pack sizes of 24, and 32.

Paracetamol 500 mg Capsules PL 44041/0196 are to be available in PVC blister in pack sizes of 8, and 16.

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

The proposed shelf life of the product is 36 months with the recommended storage condition 'Do not store above 25°C' and 'store in a dry place and in the original package'.

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

Legal status

Prescription only medicine (POM); Pharmacy (P) medicine; General Sales List (GSL) medicine.

PL 44041/0194 is Prescription only medicine (POM)

PL 44041/0195 is Pharmacy (P) medicine

PL 44041/0196 is General Sale List (GSL)

Manufacturers

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

Qualitative and quantitative compositions

The composition of the proposed products are consistent with the details registered for the cross-reference products.

Manufacturing process & control of critical steps

The proposed manufacturing processes and process controls are consistent with the details registered for the reference products 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 products.

TSE Compliance

With the exception of gelatin, no excipients of animal or human origin are used in the final products.

Copies of the current TSE certificates for suppliers of gelatin capsules have been provided and are current in accordance with EDQM database.

These products do not contain or consist of genetically modified organisms (GMO)

V. NON-CLINICAL ASPECTS

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

VI. CLINICAL ASPECTS

As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new non-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) was provided with the application in accordance with legal requirements, including user consultation.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

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

In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

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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