Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Paracetamol 500mg Effervescent Tablets

(paracetamol)

PL 00142/1255

Accord-UK Limited (Trading style: Accord)

LAY SUMMARY

Paracetamol 500mg Effervescent Tablets

(paracetamol)

This is a summary of the Public Assessment Report (PAR) for Paracetamol 500mg 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 Effervescent Tablets in this lay summary for ease of reading.

For practical information about using Paracetamol Effervescent Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Paracetamol Effervescent Tablets and what are they used for?
This application is the same as Paracetamol 500mg Effervescent Tablets (PL 20075/0370) which is already authorised.

The Company responsible for Paracetamol 500mg Effervescent Tablets (PL 20075/0370) has agreed that the scientific data used as the basis of its grant (that of Paracetamol 500 mg Effervescent Tablets (PL 20075/0083)) can be used as the basis for the grant of an identical licence for Paracetamol Effervescent Tablets.

Paracetamol Effervescent Tablets are recommended for use in treatment of mild to moderate pain and/or fever.

How do Paracetamol Effervescent Tablets work?
Paracetamol Effervescent Tablets contain the active ingredient paracetamol, which is a mild pain killer and reduces the body temperature in fever.

How are Paracetamol Effervescent Tablets used?
The pharmaceutical form of this medicine is an effervescent tablet and the route of administration is oral (taken by mouth). The tablet(s) should be placed in a full glass of water and allowed to dissolve completely before swallowing.

The recommended dose is
Adults and children 16 years and older:
• one or two tablets every 4 – 6 hours as required, up to four times daily
• maximum dose of 8 tablets in 24 hours
• maximum single dose is 1g (2 tablets)

Adolescents 12 to 15 years:
• one tablet every 4-6 hours as required, up to four times daily
• maximum dose of 4 tablets in 24 hours
• maximum single dose is 500mg (1 tablet)

Paracetamol Effervescent Tablets should not be given to children younger than 12 years.
If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, the patient should stop the treatment and consult a doctor.

The patient should not take more medicine than the label or leaflet advises the patient to take,

For further information on how Paracetamol Effervescent Tablets are used, refer to the package leaflet and Summary of Product Characteristics 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 Effervescent Tablets have been shown in studies?
Paracetamol Effervescent Tablets are considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Paracetamol Effervescent Tablets; however, reference is made to the studies for Paracetamol 500mg Effervescent Tablets.

What are the possible side effects of Paracetamol Effervescent Tablets?
Paracetamol Effervescent Tablets are considered to be identical to the previously authorised product with the same benefits and risks.

For the full list of all side effects reported with this medicine, see Section 4 of the package leaflet or the Summary of Product Characteristics (SmPC) available on the MHRA website.

Why were Paracetamol Effervescent Tablets approved?
The MHRA decided that the benefits of Paracetamol Effervescent 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 Effervescent Tablets?
A Risk Management Plan (RMP) has been developed to ensure that Paracetamol Effervescent Tablets is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Paracetamol Effervescent Tablets
A marketing authorisation was granted in the UK on 30 April 2020.

The full PAR for Paracetamol Effervescent Tablets follows this summary.

This summary was last updated in June 2020

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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 500mg Effervescent Tablets (PL 00142/1255) could be approved.

The product is approved for the following indication:

- Treatment of mild to moderate pain and/or fever.

Paracetamol is a pain reliever and reduces temperature in the case of fever.

This is a national abridged application submitted under Article 10c of Directive 2001/83/EC, as amended (an informed consent application). The application cross-refers to the reference product Paracetamol 500mg Effervescent Tablets (PL 20075/0370), currently held by and originally granted to the Marketing Authorisation Holder Accord Healthcare Limited on 31 January 2014. Paracetamol 500mg Effervescent Tablets (PL 20075/0370) was granted as an Article 10c application cross-referring to Paracetamol 500 mg Effervescent Tablets (PL 20075/0083), which was granted on 06 November 2009.

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 marketing authorisation was granted on 30 April 2020.

II. EXPERT REPORT

The applicant cross-refers to the data for Paracetamol 500mg Effervescent Tablets (PL 20075/0370; Accord Healthcare Limited), to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPC is based on that of Paracetamol 500mg Effervescent Tablets (PL 20075/0370), dated 10/2019, updated as appropriate to reflect current scientific standards and the proposed legal status.

PATIENT INFORMATION LEAFLET

A leaflet text and/or mock-up has been provided which has been aligned with that for Paracetamol 500mg Effervescent Tablets (PL 20075/0370), dated for 09/2019. The user test report submitted for PL 20075/0083 has been provided.

LABEL

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

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification

The source of the active substance is 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

The product is an effervescent tablet, which contains 500 mg paracetamol in each tablet and is for oral use.

Paracetamol 500mg Effervescent Tablets are available in:

1. white opaque plain polypropylene tubes, each with a white opaque tamper evident polyethylene cap with inbuilt desiccant, containing 8, 10, 20 or 24 tablets.
   Pack sizes: 20 (1 x 20) tablets per carton, 10 (1 x 10) tablets per carton, 16 (2 x 8) tablets per carton, 30 (3 x 10) tablets per carton, 24 (3 x 8) tablets per carton and 24 (1 x 24) tablets per carton.
2. paper/polyethylene/aluminium/surlyn strips each containing 4 or 10 tablets, in pack sizes of 10, 16, 20, 24 and 30 tablets per carton.

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

The proposed shelf life of the product is 2 years for the unopened product (polypropylene tube and strips) and the in-use shelf-life is 1 month after the first date of opening the polypropylene tube. The special storage conditions are ‘Store below 30°. Keep the polypropylene tube tightly closed. Store in the original container to protect from the moisture and light.’

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 composition

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 specification

The proposed finished product specification is 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 product.

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

V. NON-CLINICAL ASPECTS

As this application is submitted under Article 10c of Directive 2001/83/EC, 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 Article 10c of Directive 2001/83/EC, 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 Directive 2001/83/EC, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION

A user consultation with target patient groups on the Patient Information Leaflet (PIL) has been performed on the basis of a bridging report making reference to Paracetamol 500 mg Effervescent Tablets (PL 20075/0083; Accord Healthcare Limited). The bridging report submitted by the applicant is acceptable.

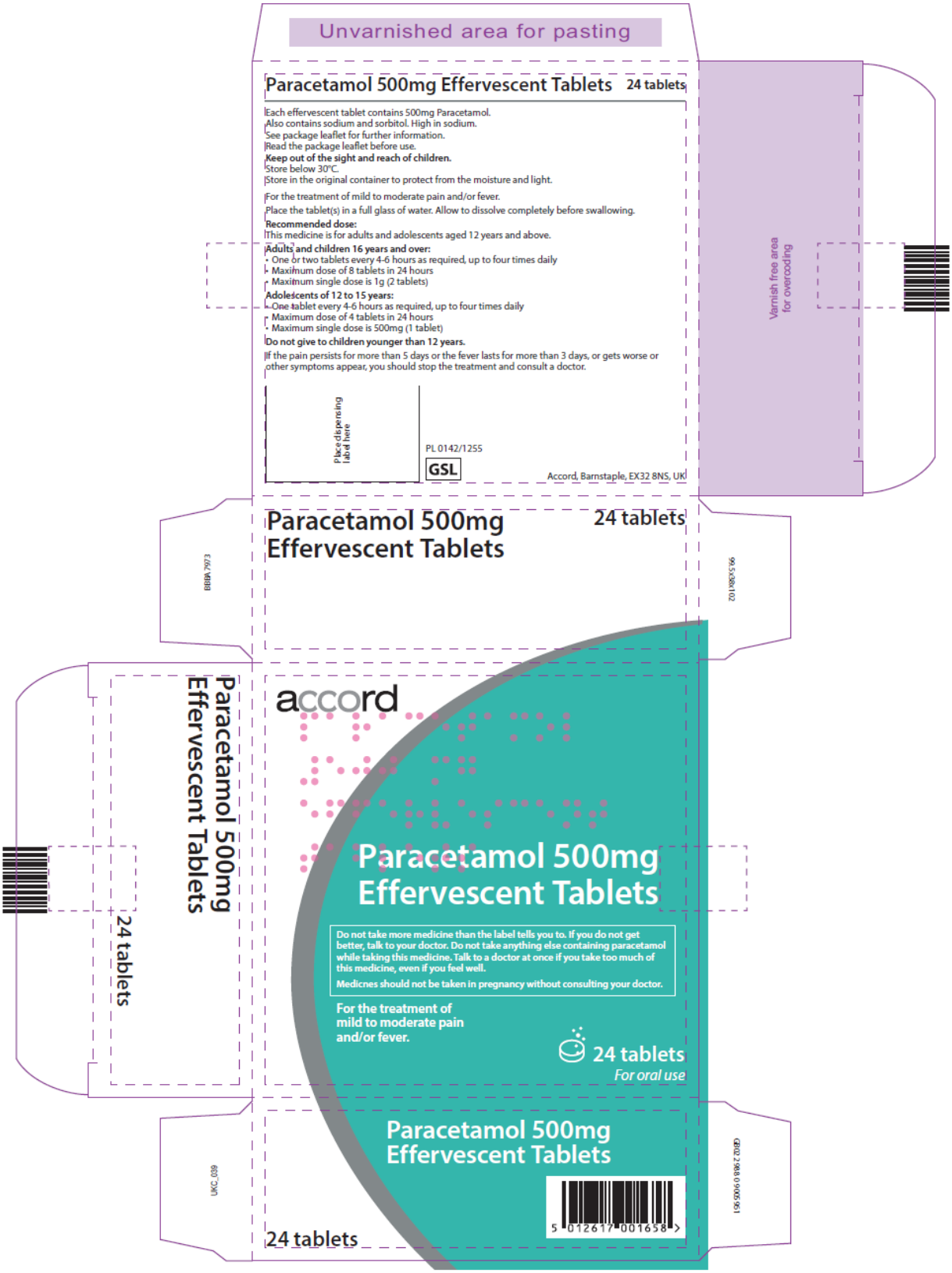
IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

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 Directive 2012/84/EU, 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 UK licensing are provided below.


Unvarnished area for pasting
Paracetamol 500mg Effervescent Tablets 24 tablets
Each effervescent tablet contains 500mg Paracetamol.
Also contains sodium and sorbitol. High in sodium.
See package leaflet for further information.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Store below 30°C.
Store in the original container to protect from the moisture and light.
For the treatment of mild to moderate pain and/or fever.
Place the tablet(s) in a full glass of water. Allow to dissolve completely before swallowing.
Recommended dose:
This medicine is for adults and adolescents aged 12 years and above.
Adults and children 16 years and over:
• One or two tablets every 4-6 hours as required, up to four times daily
• Maximum dose of 8 tablets in 24 hours
• Maximum single dose is 1g (2 tablets)
Adolescents of 12 to 15 years:
• One tablet every 4-6 hours as required, up to four times daily
• Maximum dose of 4 tablets in 24 hours
• Maximum single dose is 500mg (1 tablet)
Do not give to children younger than 12 years.
If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.
Place dispensing label here
PL 0142/1255
GSL
Accord, Barnstaple, EX32 8NS, UK
Varnish free area for overcoding
Paracetamol 500mg Effervescent Tablets 24 tablets
accord
Paracetamol 500mg Effervescent Tablets
Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Do not take anything else containing paracetamol while taking this medicine. Talk to a doctor at once if you take too much of this medicine, even if you feel well.
Medicnes should not be taken in pregnancy without consulting your doctor.
For the treatment of mild to moderate pain and/or fever.
24 tablets
For oral use
Paracetamol 500mg Effervescent Tablets
24 tablets
5 012617 001658
24 tablets
Paracetamol 500mg Effervescent Tablets
24 tablets

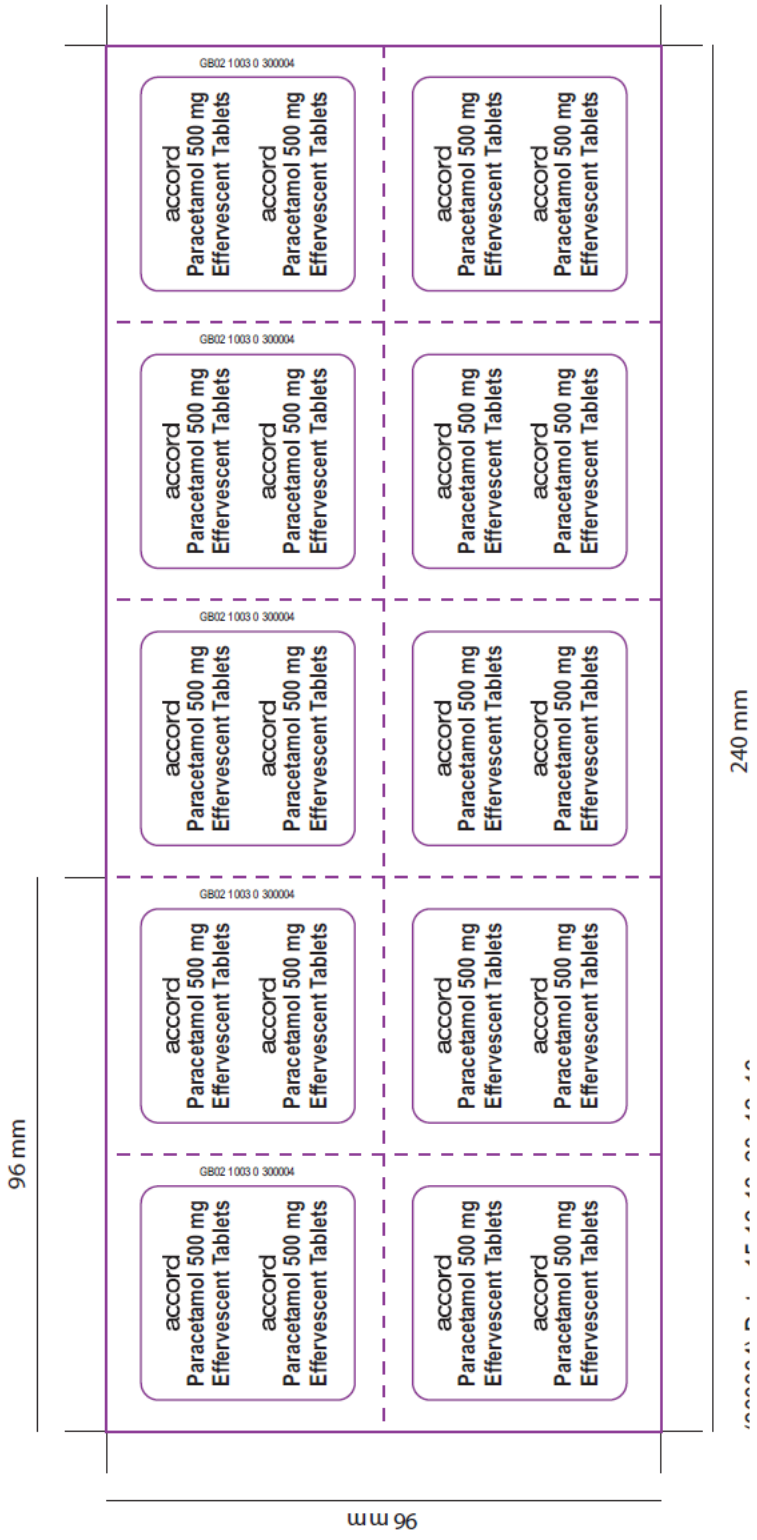

GB02 1003 0 300004
accord
Paracetamol 500 mg
Effervescent Tablets
96 mm
240 mm
96 mm

TABLE OF CONTENT OF THE PAR UPDATE

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**