Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Aspirin 75 mg Dispersible Tablets

(aspirin)

Product Licence Number: PL 00142/1252

Accord-UK Ltd (Trading style: Accord)

LAY SUMMARY

Aspirin 75 mg Dispersible Tablets

(aspirin)

This is a summary of the Public Assessment Report (PAR) for Aspirin 75 mg Dispersible 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 Aspirin Tablets in this lay summary for ease of reading.

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

What are Aspirin Tablets and what are they used for?
This application is the same as Dispersible Aspirin 75 mg Tablets BP (PL 0142/0377), which is already authorised.

The Company responsible for Dispersible Aspirin 75 mg Tablets BP has agreed that its scientific data can be used as the basis for the grant of an identical licence for Aspirin Tablets.

Aspirin Tablets are used to help heart attack and stroke in patients who have previously suffered such events, in patients who have unstable angina following by-pass surgery.

How do Aspirin Tablets work?
Aspirin Tablets contain the active ingredient aspirin, which belongs to a group of medicines that have analgesic pain relieving, anti-inflammatory (inflammation reducing) and anti-pyretic (temperature reducing properties). Aspirin also acts on the blood, helping to prevent the formation of blood clots.

How are Aspirin Tablets used?
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth). The tablets should be dispersed in a glass of water and drink.

Patients should take this medicine exactly as a doctor has told them. They should check with a doctor or pharmacist if they are not sure.

The recommended dose in adults for long-term use is 1-2 tablets (75-150 mg) once a day. In some circumstances a higher dose may be appropriate, especially in the short-term, and up to 4 tablets (300 mg) a day may be used on the advice of a doctor.

This medicine is not recommended in children and adolescents under 16 years old.

For further information on how Aspirin Tablets are 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 Aspirin Tablets have been shown in studies?
Aspirin Tablets are considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Aspirin Tablets, however, reference is made to the studies for Dispersible Aspirin 75 mg Tablets BP.

What are the possible side effects of Aspirin 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 behalf of someone else they care for, directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Aspirin Tablets are considered to be identical to the previously authorised product with the same benefits and risks.

Why were Aspirin Tablets approved?
The MHRA decided that the benefits of Aspirin 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 Aspirin Tablets?
A Risk Management Plan (RMP) has been developed to ensure that Aspirin Tablets are used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL, 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 Aspirin Tablets
A Marketing Authorisation was granted in the United Kingdom (UK) on 08 February 2021.

The full PAR for Aspirin Tablets follows this summary.

This summary was last updated in July 2021.

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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 Aspirin 75 mg Dispersible Tablets (PL 00142/1252) could be approved.

The product is approved for the secondary prevention of thrombotic cerebrovascular or cardiovascular disease, following by-pass surgery and in patients suffering from unstable angina.

Aspirin is an anti-inflammatory analgesic and antipyretic. Aspirin inhibits platelet aggregation.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400 mg was taken within 8 hours before or within 30 minutes after immediate release aspirin (81 mg), a decreased effect of aspirin on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of *ex vivo* data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulations 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to the reference product Dispersible Aspirin 75 mg Tablets BP (PL 0142/0377), which was originally granted in the UK to the Marketing Authorisation Holder Accord-UK Ltd (PL 00142/5601R) on 24 April 1972.

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 versions 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 (UK) on 08 February 2021.

II. EXPERT REPORT

The applicant cross-refers to the data for Dispersible Aspirin 75 mg Tablets BP (PL 00142/0377; Accord-UK Ltd), 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 in line with that for Dispersible Aspirin 75 mg Tablets BP (PL 00142/0377), dated 09 December 2019.

PATIENT INFORMATION LEAFLET
A leaflet mock-up has been provided which has been aligned with that for Dispersible Aspirin 75 mg Tablets BP (PL 00142/0377), dated for December 2019. The user test report submitted for PL 00142/1252 has been provided.

LABEL
Label text 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
Aspirin 75 mg Dispersible Tablets are available in either white polyvinyl (PVC)/polyethylene (PE)/polyvinyldichloride (PVdC) or in soft aluminium glassine paper. Compliant with BS EN 14375. The pack sizes are 28, 30, 56, 60 and 100 Tablets.

PE tablet container with a child-resistant polypropylene (PP) closure. A 2 g silica gel container is included in each pack. Compliant with ISO 8317. The pack size is 100 Tablets.

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 tablet container and 1 year for blister pack with the recommended storage conditions ‘Store below 25°C in a dry place’ and ‘Keep tightly closed’.

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

Legal status
Pharmacy (P) medicine.

Manufacturers
The proposed manufacturing site 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
With the exception of lactose, no excipients of animal or human origin are used in the final product.

The supplier of lactose has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.

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 Regulations 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 Regulations 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 Regulations 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 Dispersible Aspirin 75mg Tablets BP (PL 00142/0377-0070; Accord-UK Ltd). 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.

The following text is the currently approved label text. No label mock-ups have been provided for this product. In accordance with legal requirements, this product shall not be marketed until approval of the full-colour label mock-ups has been obtained.

MINIMUM PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

carton

1. NAME OF THE MEDICINAL PRODUCT

Aspirin 75mg Dispersible Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 75mg Aspirin

3. LIST OF EXCIPIENTS

Also contains lactose - see leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

28 tablets
30 tablets
56 tablets
60 tablets
100 tablets

For oral use

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use,
Directions: Disperse in water before use:

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Your doctor's advice should be sought before starting long-term aspirin treatment. Used to help prevent heart attacks & stroke in previous sufferers & in patients who have unstable angina & after by-pass surgery.
Medicines should not be taken in pregnancy without consulting your doctor. Aspirin should be avoided in late pregnancy and generally during breast feeding.
Do not take if you have or have had a stomach ulcer. Do not exceed the stated dose.
If you do not get better talk to your doctor
Do not give to children under 16 years of age unless your doctor tells you to.

8. EXPIRY DATE

Exp

9. SPECIAL STORAGE CONDITIONS

Store below 25°C in a dry place.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Accord logo

Accord, Barnstaple, EX32 8NS, UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 0142/1252

13. BATCH NUMBER

Batch:
Manufd:

14. GENERAL CLASSIFICATION FOR SUPPLY

P.

15. INSTRUCTIONS ON USE

Take 1-2 tablets once daily (up to 4 tablets on the advice of a doctor).

16. INFORMATION IN BRAILLE

Braille reads: aspirin dispersible 75 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]

ADDITIONAL INFORMATION

Place dispensing label here (on back panel)
READ ENCLOSED LEAFLET (on flaps)
Illustration –
Barcode
Carton reference number
Carton size

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Aspirin 75mg Dispersible Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Accord logo

3. EXPIRY DATE

4. BATCH NUMBER

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE MEDICINAL PRODUCT AND ROUTES OF ADMINISTRATION

Aspirin 75mg Dispersible Tablets

2. METHOD OF ADMINISTRATION

Directions: Disperse in water before use.
Read the package leaflet before use.

3. EXPIRY DATE

4. BATCH NUMBER, DONATION AND PRODUCT CODES

PL 0142/1252

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

100 tablets
For oral use

OTHER

Each tablet contains 75mg Aspirin.
Also contains lactose - see leaflet for further information.
Dosage: as directed by practitioner.
Keep out of the sight and reach of children.
If you do not get better talk to your doctor
Do not give to children under 16 years of age unless your doctor tells you to.

Keep airtight at all times and store below 25°C in a dry place.
Barcode *(EAN number)*
Accord, Barnstaple, EX32 8NS, UK

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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**