Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedures

Abiraterone Accord 250 mg and 500 mg tablets

(abiraterone acetate)

Product Licence Numbers: PLGB 20075/1480-1481

Accord Healthcare Limited

LAY SUMMARY
Abiraterone Accord 250 mg and 500 mg tablets (abiraterone acetate)

This is a summary of the Public Assessment Report (PAR) for Abiraterone Accord 250 mg and 500 mg tablets. It explains how these products were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Abiraterone Accord in this lay summary for ease of reading.

For practical information about using Abiraterone Accord, patients should read the Patient Information Leaflets (PILs) or contact their doctor or pharmacist.

What is Abiraterone Accord and what is it used for?
These products have been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 25 February 2021 (EMEA/H/C/005408/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

Abiraterone Accord is used to treat prostate cancer in adult men that has spread to other parts of the body.

When Abiraterone Accord is prescribed for the early stage of disease where it is still responding to hormone therapy, it is used with a treatment that lowers testosterone (androgen deprivation therapy).

When patients take this medicine, a doctor will also prescribe another medicine called prednisone or prednisolone. This is to lower the chances of getting high blood pressure, having too much water in the body (fluid retention), or having reduced levels of a chemical known as potassium in the blood.

How does Abiraterone Accord work?
Abiraterone Accord contains the active ingredient abiraterone acetate. This medicine stops the body from making testosterone; this can slow the growth of prostate cancer.

How is Abiraterone Accord used?
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth). The tablets are swallowed with water without breaking. This medicine should not be taken with food. Abiraterone Accord should be taken at least 1 hour before or at least 2 hours after eating.

For 250 mg formulation
The recommended dose is 1000 mg (4 tablets) once a day.

For 500 mg formulation
The recommended dose is 1000 mg (2 tablets) once a day.

Abiraterone Accord is taken with a medicine called prednisone or prednisolone. Patients should take the prednisone or prednisolone exactly as a doctor has told them.

Patients need to take prednisone or prednisolone every day while taking Abiraterone Accord.

The amount of prednisone or prednisolone patients take may need to change if they have a medical emergency.

The patient's doctor will tell them if they need to change the amount of prednisone or prednisolone to take. The patient should not stop taking prednisone or prednisolone unless a doctor tells them to.

The patient's doctor may also prescribe other medicines while they are taking Abiraterone Accord and prednisone or prednisolone.

For further information on how Abiraterone Accord is used, refer to the PILs and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with 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 are the possible side effects of Abiraterone Accord?
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 the patient by someone else who cares for them, 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.

Why was Abiraterone Accord approved?
It was concluded that Abiraterone Accord has been shown to be effective in the treatment of prostate cancer in adult men that has spread to other parts of the body. Furthermore, the side effects observed with use of these products are considered to be typical for this type of treatment. Therefore, the MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

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

The following safety concerns have been recognised for Abiraterone Accord:

The important identified risks are hepatotoxicity, cardiac disorders, osteoporosis including osteoporosis-related fractures, rhabdomyolysis/myopathy, allergic alveolitis and increased exposure with food.

The important potential risks are anaemia, cataract and drug-drug interaction (CYP2D6).

The missing information are:

- Use in patients with active or symptomatic viral hepatitis
- Use in patients with moderate/severe hepatic impairment and chronic liver disease
- Use in patients with severe renal impairment
- Use in patients with heart disease as evidenced by myocardial infarction, or arterial thrombotic events in the past 6 months, severe or unstable angina, or New York Heart Association Class III or IV heart disease or cardiac ejection fraction measurement of <50%

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

Other information about Abiraterone Accord

Marketing authorisations were granted in Great Britain on 15 December 2021.

The full PAR for Abiraterone Accord follows this summary.

This summary was last updated in February 2022.

TABLE OF CONTENTS

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 Abiraterone Accord 250 mg and 500 mg tablets (PLGB 20075/1480-1481) could be approved.

These products are indicated with prednisone or prednisolone for the treatment of:

- newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)
- metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated
- mCRPC in adult men whose disease has progressed on or after a docetaxel based chemotherapy regimen.

Abiraterone acetate is converted in vivo to abiraterone, an androgen biosynthesis inhibitor. Specifically, abiraterone selectively inhibits the enzyme 17 α hydroxylase/C17,20 lyase (CYP17). This enzyme is expressed in and is required for androgen biosynthesis in testicular, adrenal and prostatic tumour tissues. CYP17 catalyses the conversion of pregnenolone and progesterone into testosterone precursors, DHEA and androstenedione, respectively, by 17 α hydroxylation and cleavage of the C17,20 bond. CYP17 inhibition also results in increased mineralocorticoid production by the adrenals.

Androgen sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Androgen deprivation therapies, such as treatment with LHRH analogues or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumour. Treatment with abiraterone decreases serum testosterone to undetectable levels (using commercial assays) when given with LHRH analogues (or orchiectomy).

These products have been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 25 February 2021 (EMEA/H/C/005408/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Report, available on the EMA website.

These applications were approved under Regulation 51B of The Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

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.

Marketing Authorisations were granted on 15 December 2021.

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

The SmPCs are in line with current guidelines and are satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and are satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for these applications are satisfactory.

The grant of marketing authorisations is recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for these applications are satisfactory.

The grant of marketing authorisations is recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for these applications are satisfactory.

The grant of marketing authorisations is recommended.

VI. 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.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflets (PILs) have been provided with the applications in accordance with legal requirements.

The PILs have 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 Solifenacin succinate 5/10 mg film-coated tablets and Zytiga 250/500 mg tablets. The bridging report submitted by the applicant is acceptable.

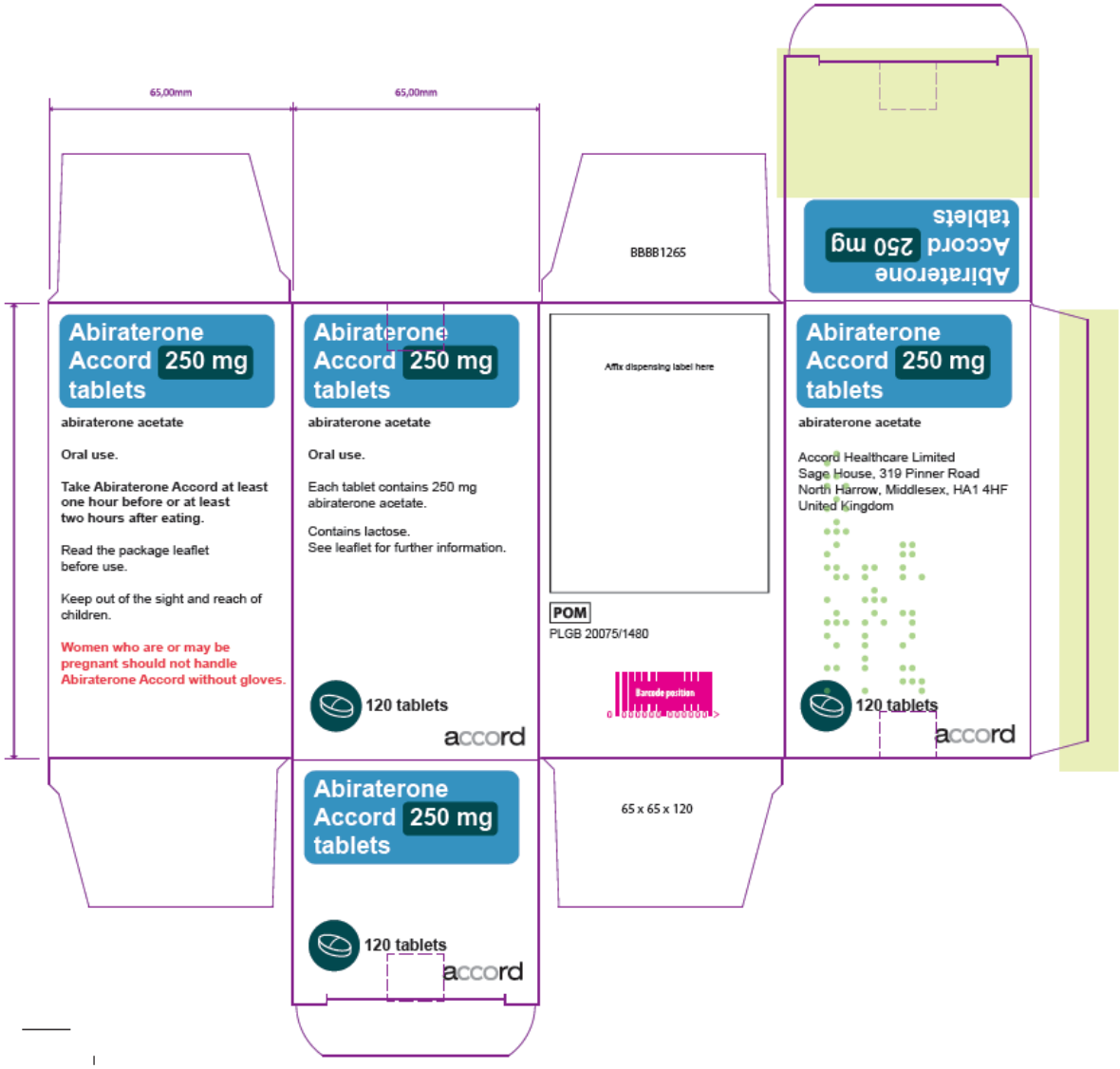
VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

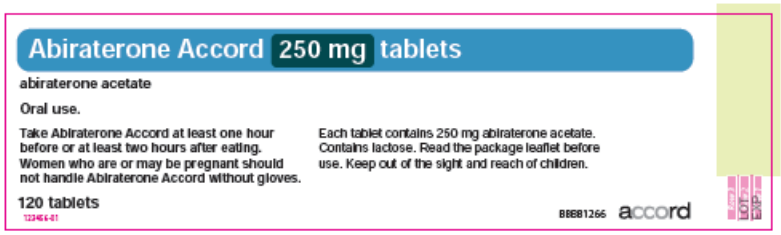
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

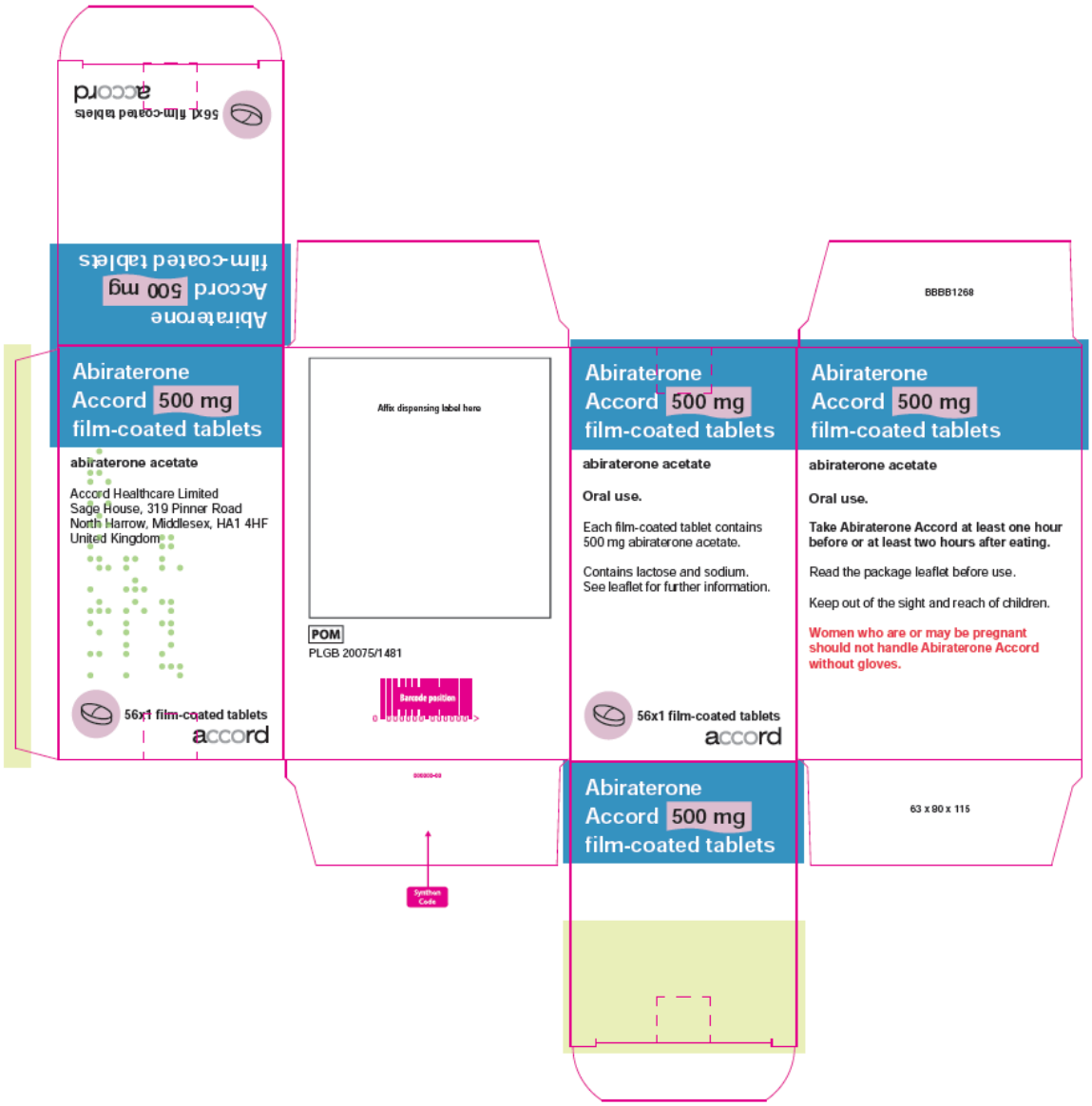
The SmPCs, PILs and labelling are satisfactory.

In accordance with Regulation 203(2) of The Human Medicines Regulation 2012, as amended, the current approved GB versions of the SmPCs and PILs for these products are available on the MHRA website.

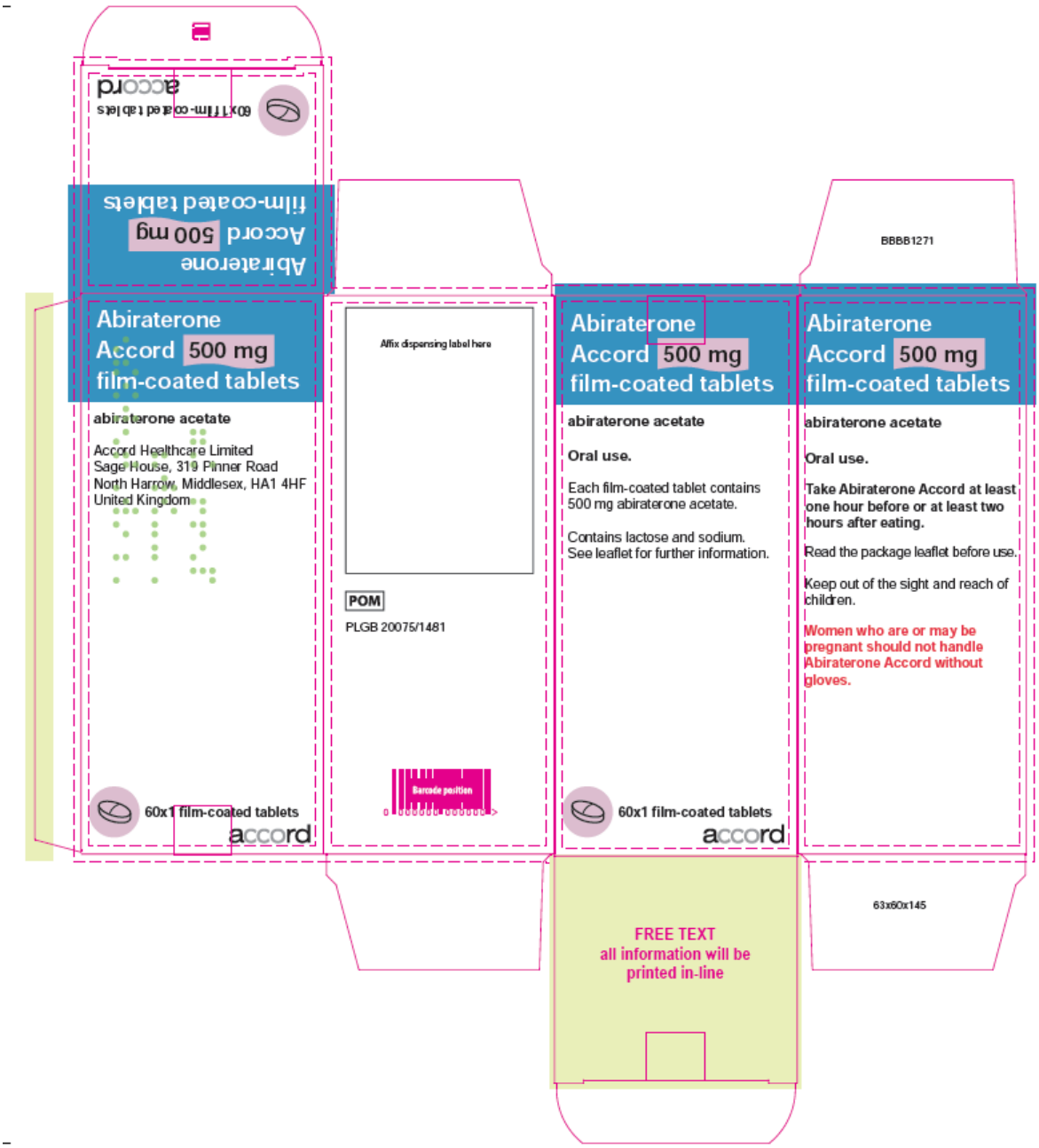
Representative copies of the labels at the time of UK licensing are provided below.






Abiraterone Accord 500 mg film-coated tablets
abiraterone acetate
Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF
United Kingdom
56x1 film-coated tablets
accord
Affix dispensing label here
POM
PLGB 20075/1481
Barcode position
Oral use.
Each film-coated tablet contains 500 mg abiraterone acetate.
Contains lactose and sodium. See leaflet for further information.
Take Abiraterone Accord at least one hour before or at least two hours after eating.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Women who are or may be pregnant should not handle Abiraterone Accord without gloves.
BBBB1268
63 x 90 x 115
Synthon Code


Abiraterone Accord 500 mg tablets
abiraterone acetate
Lot:
EXP:
accord
BBBB1270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60x1 film-coated tablets
accord
Affix dispensing label here
POM
PLGB 20075/1481
Barcode position
Abiraterone Accord 500 mg film-coated tablets
abiraterone acetate
Oral use.
Each film-coated tablet contains 500 mg abiraterone acetate.
Contains lactose and sodium. See leaflet for further information.
60x1 film-coated tablets
accord
BBBB1271
Abiraterone Accord 500 mg film-coated tablets
abiraterone acetate
Oral use.
Take Abiraterone Accord at least one hour before or at least two hours after eating.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Women who are or may be pregnant should not handle Abiraterone Accord without gloves.
63x60x145
FREE TEXT
all information will be printed in-line

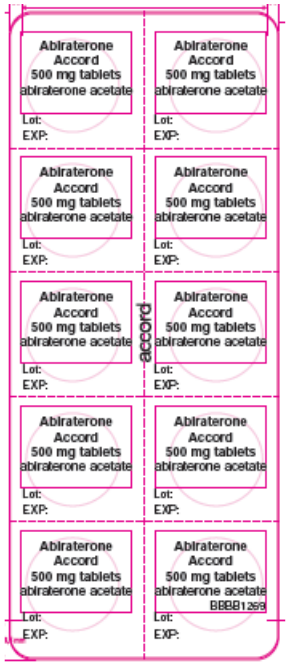
Abiraterone Accord 500 mg tablets abiraterone acetate
Lot:
EXP:
accord
BBBB1269

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 SmPCs and/or PIL available on the MHRA website.

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