Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Bisacodyl 5 mg Tablets

(Bisacodyl)

Product Licence Number: PL 49565/0018

Rudipharm Limited

LAY SUMMARY
Bisacodyl 5 mg Tablets
(Bisacodyl)

This is a summary of the Public Assessment Report (PAR) for Bisacodyl 5 mg 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 Bisacodyl Tablets in this lay summary for ease of reading.

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

What are Bisacodyl Tablets and what are they used for?
This application is the same as Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets (PL 21880/0019), which is already authorised.

The Company responsible for Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets has agreed that its scientific data can be used as the basis for the grant of an identical licence for Bisacodyl Tablets.

Bisacodyl Tablets are used for the short-term relief of occasional constipation.

How do Bisacodyl Tablets work?
Bisacodyl Tablets contain the active ingredient bisacodyl, which belongs to a group of medicines known as stimulant laxatives, which increases bowel movement of waste products through the body helping patients go to the toilet. This medicine does not help with weight loss.

How are Bisacodyl Tablets used?
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth). The tablets must be swallowed whole with water. The tablets should not be chewed or crushed.

Bisacodyl tablets are for short term use. Patients should not use this medicine everyday for more than 5 days.

Talk to your doctor or pharmacist if you still have problems after 5 days. Overuse can be harmful.

Children aged 12 years or younger
Bisacodyl must not be used in children under 12 years of age.

Dosage for short term treatment of constipation:
Adults (including the elderly) and children 12 years and over will start with 1 tablet and increase to 2 if necessary.

For further information on how Bisacodyl Tablets are used, refer to the package leaflet 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 Bisacodyl Tablets have been shown in studies?
Bisacodyl Tablets are considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Bisacodyl Tablets, however, reference is made to the studies for Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets.

What are the possible side effects of Bisacodyl Tablets?
Bisacodyl 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 SmPC available on the MHRA website.

Why were Bisacodyl Tablets approved?
The MHRA decided that the benefits of Bisacodyl 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 Bisacodyl Tablets?
A Risk Management Plan (RMP) has been developed to ensure that Bisacodyl Tablets are 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 Bisacodyl Tablets
A Marketing Authorisation was granted in the UK on 22 January 2021.

The full PAR for Bisacodyl Tablets follows this summary.

This summary was last updated in March 2021.

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 application for Bisacodyl 5 mg Tablets (PL 49565/0018) could be approved.

The product is approved for the short-term relief of occasional constipation.

Bisacodyl is a locally acting laxative of the triarylmethane group, which, after bacterial cleavage in the colon, has the dual action of stimulating the mucosa of both the large intestine causing peristalsis and of the rectum causing increased motility and a feeling of rectal fullness.

The rectal effect may help to restore the "call to stool" although its clinical relevance remains to be established.

This is a national abridged application submitted under Article 10c of Directive 2001/83/EC, as amended (regulation 56 of The Human Medicines Regulations 2012) (an informed consent application). The application cross-refers to the reference product Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets (PL 21880/0019), currently held by Medreich PLC, which was originally granted in the UK to the Marketing Authorisation Holder Sussex Pharmaceuticals Limited (PL 05544/0087) on 05 April 1994 and then to Wrafton Laboratories Limited (PL 00010/0266) on 13 November 2003.

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 22 January 2021.

II. EXPERT REPORT

The applicant cross-refers to the data for Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets (PL 21880/0019; Medreich PLC), 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 Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets (PL 21880/0019) dated 18 February 2020.

PATIENT INFORMATION LEAFLET
A leaflet mock-up has been provided which has been aligned with that for Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets (PL 21880/0019), dated for 18 February 2020. The user test report submitted for PL 49565/0018 has been provided.

LABEL
Label 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
Bisacodyl Tablets are available in packs of 500 and 1000 tablets in securitainers. The container is made up of a high-density polypropylene body and low-density polyethylene cap.
The product is also available in blister packs of 20, 40, 60 and 100 tablets.

The tablets are packed into polyvinylchloride (PVC)/aluminium foil blister packs.
Not all pack sizes may be marketed.

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

The proposed shelf life of the product is 3 years for securitainers with storage conditions “Do not store above 25^{o}C and protect from light” and 24 months for the blister with storage conditions “Do not store above 25^{o}C” and “Store in the original package” are proposed.

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 is 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 process 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 proposed finished product specification is 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.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

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, (regulation 56 of The Human Medicines Regulations 2012) (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, (regulation 56 of The Human Medicines Regulations 2012) (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 (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 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 Bisacodyl 5 mg Tablets/Boots Constipation Relief 5 mg Gastro-resistant Tablets (PL 21880/0019; Medreich PLC). The bridging report submitted by the applicant is acceptable.

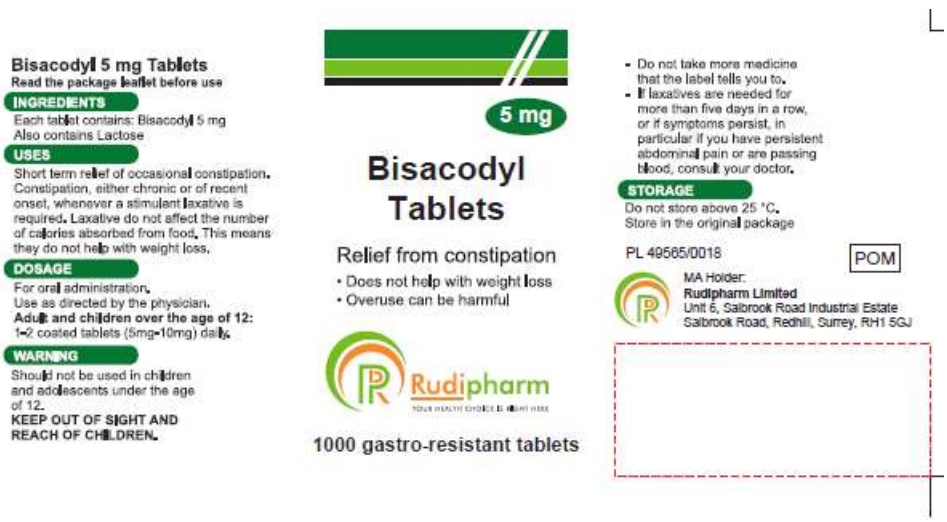
IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

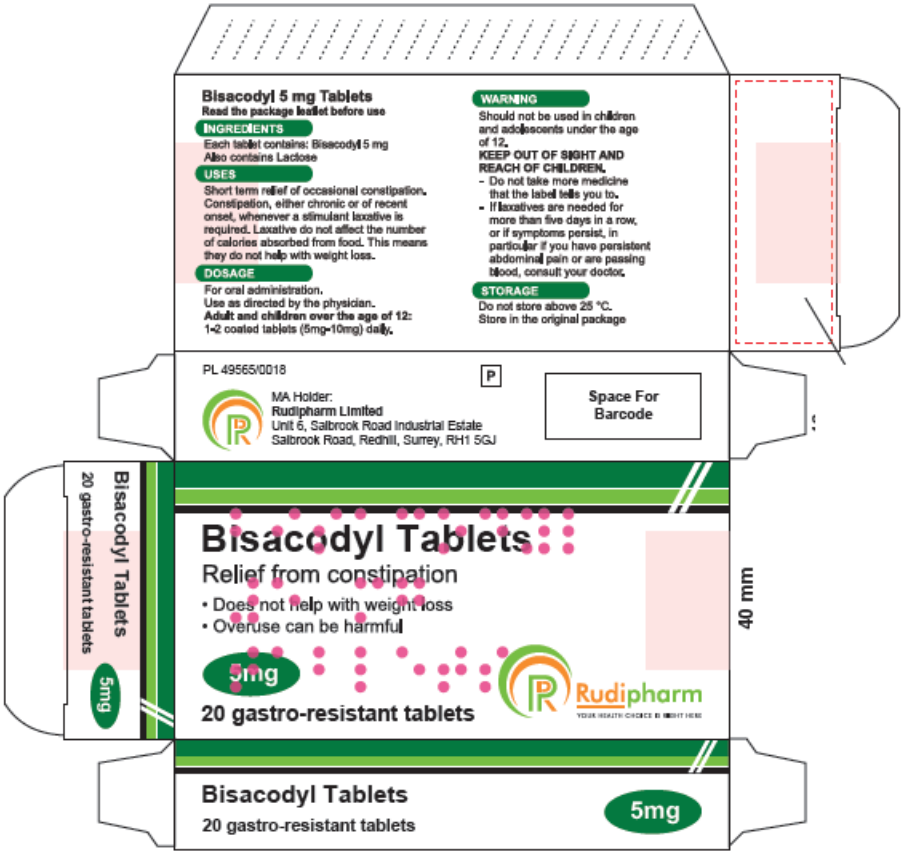
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

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 2010/84/EU (regulation 203 of The Human Medicines Regulations 2012), 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.




Bisacodyl 5 mg Tablets
Read the package leaflet before use
INGREDIENTS
Each tablet contains: Bisacodyl 5 mg
Also contains Lactose
USES
Short term relief of occasional constipation.
Constipation, either chronic or of recent onset, whenever a stimulant laxative is required. Laxative do not affect the number of calories absorbed from food. This means they do not help with weight loss.
DOSAGE
For oral administration.
Use as directed by the physician.
Adult and children over the age of 12:
1-2 coated tablets (5mg-10mg) daily.
WARNING
Should not be used in children and adolescents under the age of 12.
KEEP OUT OF SIGHT AND REACH OF CHILDREN.
- Do not take more medicine that the label tells you to.
- If laxatives are needed for more than five days in a row, or if symptoms persist, in particular if you have persistent abdominal pain or are passing blood, consult your doctor.
STORAGE
Do not store above 25 °C.
Store in the original package
PL 49565/0018
P
MA Holder:
Rudipharm Limited
Unit 6, Saltbrook Road Industrial Estate
Saltbrook Road, Redhill, Surrey, RH1 5GJ
Space For Barcode
Bisacodyl Tablets
20 gastro-resistant tablets
5mg
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Relief from constipation
• Does not help with weight loss
• Overuse can be harmful
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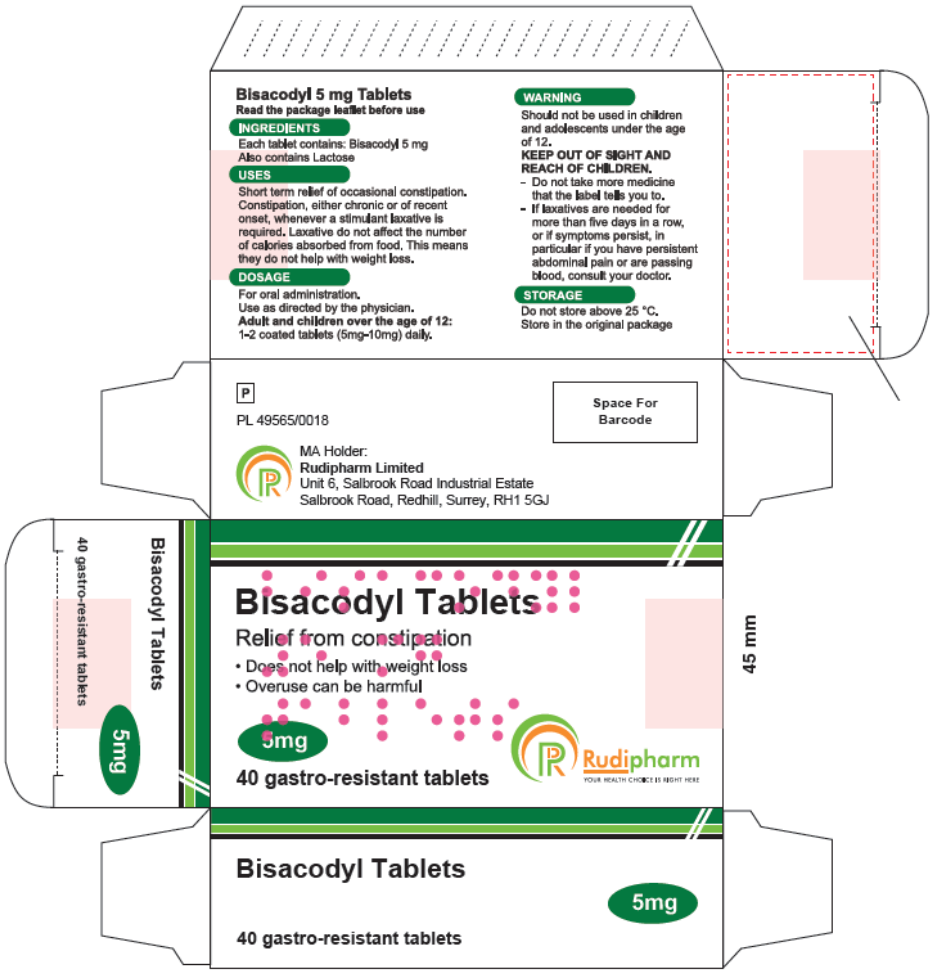
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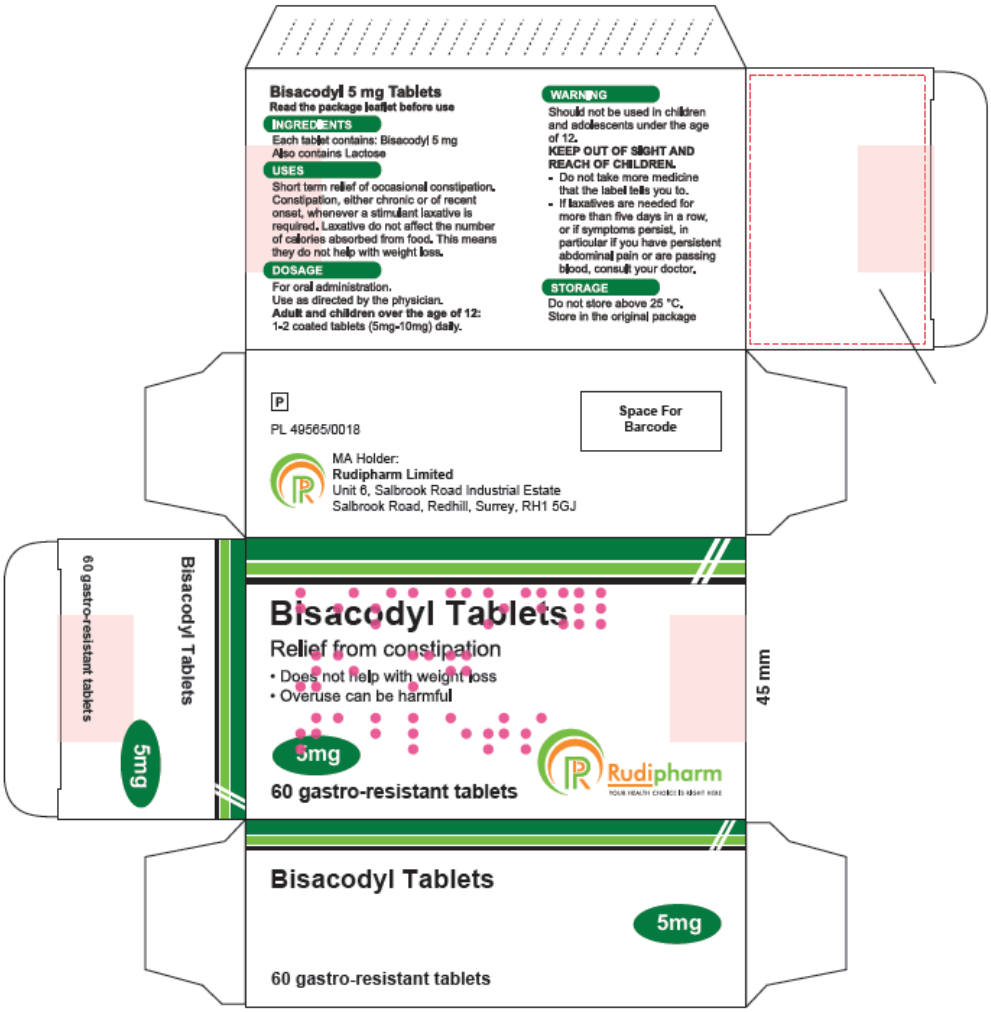
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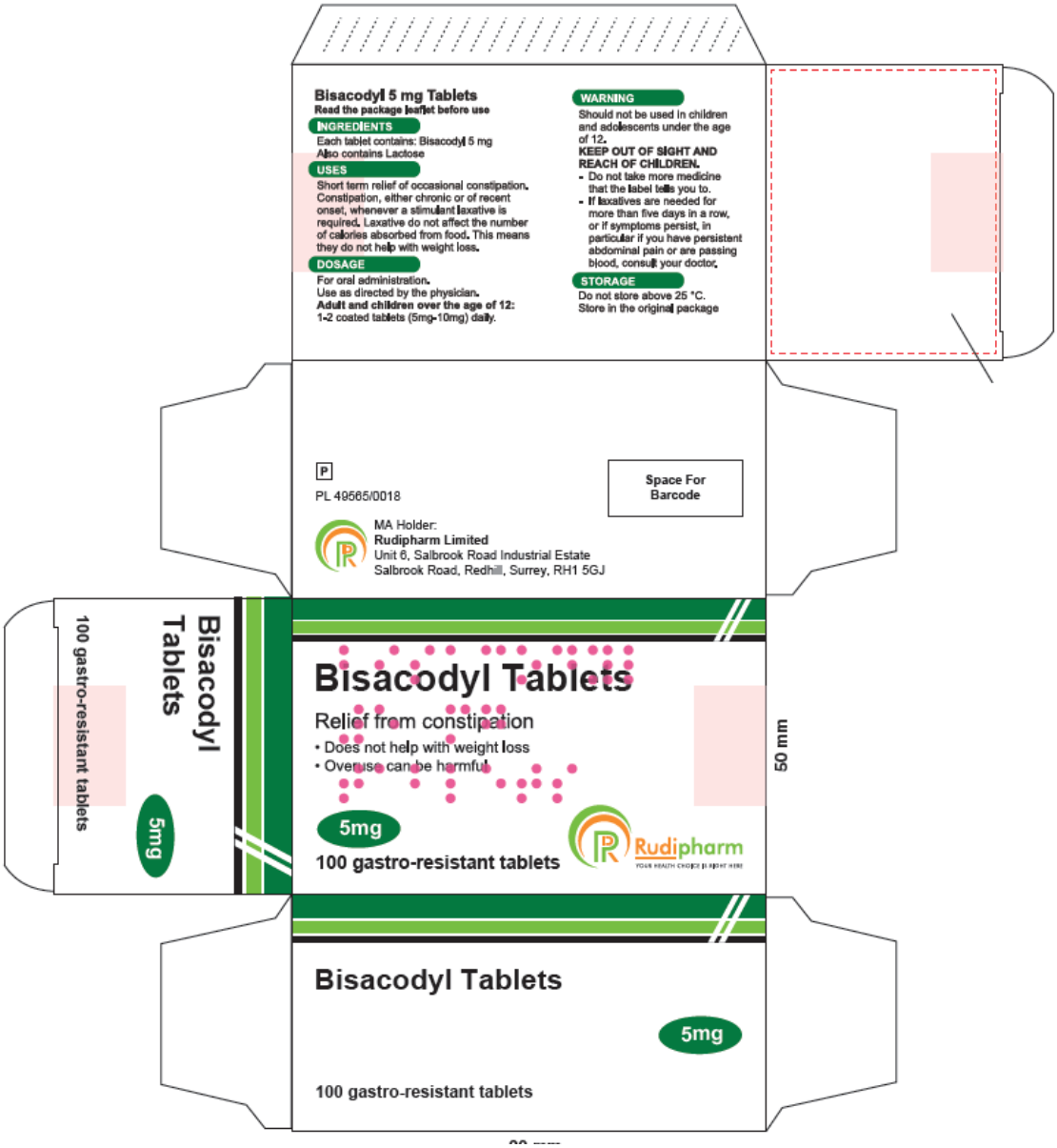
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Rudipharm
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Bisacodyl Tablets
5mg
100 gastro-resistant tablets

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**