BUSCOPAN CRAMPS RELIEF 10 MG TABLETS
(hyoscine butylbromide)

PL 00015/0348

UKPAR

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LAY SUMMARY
Buscopan Cramps Relief 10 mg Tablets
(hyoscine butylbromide)

This is a summary of the public assessment report (PAR) for Buscopan Cramps Relief 10 mg Tablets (PL 00015/0348). It explains how the application for Buscopan Cramps Relief 10 mg Tablets was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Buscopan Cramps Relief 10 mg Tablets. For practical information about using Buscopan Cramps Relief 10 mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Buscopan Cramps Relief 10 mg Tablets and what are they used for?

Buscopan Cramps Relief 10 mg Tablets belong to a group of medicines called antispasmodics. They are used to relieve stomach and bowel cramps, which cause pain and discomfort associated with your digestive tract, and in Irritable Bowel Syndrome. It may also be recommended by your doctor for spasm of the bladder and urinary tract.

This medicine is identical to Buscopan Tablets/Cramps (PL 00015/0047R), which was authorised in the UK to Boehringer Ingelheim Limited on 23 April 1985. Boehringer Ingelheim Limited has agreed that scientific data presented for Buscopan Tablets/Cramps (PL 00015/0047R) can be used for this application for Buscopan Cramps Relief 10 mg Tablets (PL 00015/0348).

How are Buscopan Cramps Relief 10 mg Tablets used?

Buscopan Cramps Relief 10 mg Tablets are for oral use. This medicine can be obtained without a prescription from a pharmacy. Buscopan Cramps Relief 10 mg Tablets should be swallowed whole with water. Buscopan Cramps Relief 10 mg Tablets must not be taken continuously for more than two weeks.

How do Buscopan Cramps Relief 10 mg Tablets work?

Buscopan Cramps Relief 10 mg Tablets contain the active ingredient hyoscine butylbromide. Buscopan Cramps Relief 10 mg Tablets are an antispasmodic medicine. They work by relaxing the cramping muscles of the stomach and bowel, or urinary tract. The muscles of the stomach and bowel appear to be very sensitive to stress, eating and drinking habits, food allergies or intolerances, stimulants such as coffee and hormonal factors. These factors can cause the muscles in the wall of the stomach or bowel to tighten and trigger painful abdominal cramps (or spasms), bloating with excess wind and abdominal discomfort.

How have Buscopan Cramps Relief 10 mg Tablets been studied?

This application is identical to the previously granted application for Buscopan Tablets/Cramps (PL 00015/0047R; Boehringer Ingelheim Limited). The applicant referred to data provided by Boehringer Ingelheim Limited for the grant of Buscopan
What are the benefits and risks of Buscopan Cramps Relief 10 mg Tablets?

Buscopan Cramps Relief 10 mg Tablets are considered identical to Buscopan Tablets and Buscopan Cramps, with benefits and risks taken as being the same as those for Buscopan Tablets and Buscopan Cramps.

Why are Buscopan Cramps Relief 10 mg Tablets approved?

No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Buscopan Cramps Relief 10 mg Tablets outweigh their risks so the grant of a Marketing Authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Buscopan Cramps Relief 10 mg Tablets?

Safety information has been included in the Summary of Product Characteristics and the package leaflet for Buscopan Cramps Relief 10 mg Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Buscopan Cramps Relief 10 mg Tablets

A Marketing Authorisation was granted in the UK on 13 January 2014. For more information about treatment with Buscopan Cramps Relief 10 mg Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in February 2014.

The full PAR for Buscopan Cramps Relief 10 mg Tablets follows this summary.
BUSCOPAN CRAMPS RELIEF 10 MG TABLETS
(PL 00015/0348)

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Buscopan Cramps Relief 10 mg Tablets (PL 00015/0348) on 13 January 2014 to Boehringer Ingelheim Limited.

This application for Buscopan Cramps Relief 10 mg Tablets was submitted as an abridged simple application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Buscopan Tablets/Cramps, which were granted a licence to Boehringer Ingelheim Limited on 23 April 1985 (PL 00015/0047R).

This medicine can be obtained without a prescription from a pharmacy (legal status P) and is indicated for the relief of spasm of the genito-urinary tract or gastro-intestinal tract and for the symptomatic relief of Irritable Bowel Syndrome. The product contains the active ingredients hyoscine butylbromide, a quaternary ammonium derivative that does not enter the central nervous system; thus, anticholinergic side effects of the central nervous system do not occur. Therefore, Buscopan Cramps Relief 10 mg Tablets exert a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genito-urinary tracts, through a peripheral anticholinergic action resulting from ganglion-blocking within the visceral wall as well as from an anti-muscarinic activity.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00015/0348
PROPRIETARY NAME: Buscopan Cramps Relief 10 mg Tablets
ACTIVE(S): Hyoscine butylbromide
COMPANY NAME: Boehringer Ingelheim Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: P

1. INTRODUCTION
This is a simple, piggyback application for Buscopan Cramps Relief 10 mg Tablets submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, as amended. The proposed MA holder is Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.

The application cross-refers to Buscopan Tablets/Cramps (PL 00015/0047R), which were granted a licence to Boehringer Ingelheim Limited on 23 April 1985 (PL 00015/0047R).

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed name of the product is Buscopan Cramps Relief 10 mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains 10mg hyoscine butylbromide.
The finished product is packaged in aluminium/polyvinylchloride blister packs containing 20 or 24 tablets.

The marketing authorisation holder has stated that not all pack sizes are intended for marketing. However, they have committed to providing the relevant licensing authority with the mock-ups for any pack size before marketing it in that country.

The proposed shelf-life (5 years) and the storage conditions (Store below 25 °C, protect from light and store in a dry place) are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the product will be available without prescription from a pharmacy (legal status P).

2.4 Marketing authorisation holder/Contact Persons/Company
Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
Beeswax white is the only ingredient of animal origin. This is consistent with the cross-reference product.
No genetically modified materials are included in this product. This is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPC is consistent with the details registered for the cross-reference product.
6. PATIENT INFORMATION LEAFLET (PIL)/CARTON

PIL
The patient information leaflet has been prepared in line with the details registered for the cross-reference product.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the products in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with this application are acceptable. From a quality perspective, a Marketing Authorisation should be granted.

NON-CLINICAL ASSESSMENT
No new non-clinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT
No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The important quality characteristics of Buscopan Cramps Relief 10 mg Tablets are identical to those for the already granted reference product. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

CLINICAL PHARMACOLOGY/EFFICACY
No new clinical pharmacology/efficacy data have been submitted with this application and none are required for an application of this type.

SAFETY
No new safety data have been submitted with this application and none are required for an application of this type.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labels are satisfactory.

Pharmacovigilance System and Risk Management Plan
The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Suitable justification has been provided for not submitting a risk management plan for this product. Safety information has been included in the Summary of Product Characteristics and the package leaflet for Buscopan Cramps Relief 10 mg Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with hyoscine butylbromide is considered to have demonstrated the therapeutic value of the product. The benefit/risk is, therefore, considered to be positive.
BUSCOPAN CRAMPS RELIEF 10 MG TABLETS

(PL 00015/0348)

STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 11 April 2012</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant, the MHRA considered the application valid on 28 May 2012</td>
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<td>3</td>
<td>Following assessment of the application, the MHRA requested further information relating to the dossiers on 27 September 2012, 23 January 2013, 23 April 2013, 28 August 2013 and 14 November 2013</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 4 October 2012, 22 March 2013, 26 July 2013, 15 October 2013 and 15 November 2013</td>
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<td>The application was determined on 013 January 2014</td>
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BUSCOPAN CRAMPS RELIEF 10 MG TABLETS

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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
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Summary of Product Characteristics and Patient Information Leaflet
The current approved UK versions of the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PILs) for these products is available on the MHRA website.
UKPAR Buscopan Cramps Relief 10 mg Tablets

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