Buscopan 10 mg Tablets
(hyoscine butylbromide)

PL 00015/0347

UKPAR

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LAY SUMMARY

Buscopan 10 mg Tablets
(hyoscine butylbromide)

This is a summary of the Public Assessment Report (PAR) for Buscopan 10 mg Tablets (PL 00015/0347). It explains how Buscopan 10 mg Tablets were assessed and their authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Buscopan 10 mg Tablets.

For practical information about using Buscopan 10 mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Buscopan 10 mg Tablets and what are they used for?
This medicine is the same as Buscopan Tablets/Cramps (PL 00015/0047R) which is already authorised in the UK. Boehringer Ingelheim Limited has used the scientific data presented for Buscopan Tablets/Cramps (PL 00015/0047R) as a basis for the grant of an identical licence for the application for Buscopan 10 mg Tablets (PL 00015/0347).

Buscopan 10 mg Tablets are used to relieve cramps in the muscles of the:
- stomach
- gut (intestine)
- bladder and the tubes that lead to the outside of the body (urinary system).

Buscopan 10 mg Tablets can also be used to relieve the symptoms of Irritable Bowel Syndrome (IBS).

How do Buscopan 10 mg Tablets work?
Buscopan 10 mg Tablets contain the active substance hyoscine butylbromide, which belongs to a group of medicines called ‘antispasmodics’.

How are Buscopan 10 mg Tablets used?
Buscopan 10 mg Tablets are taken by mouth.

Buscopan 10 mg Tablets can only be obtained with a prescription. The tablets should be taken exactly as instructed by the doctor or pharmacist. The patient should check with the doctor or pharmacist if not sure. Buscopan 10 mg Tablets should not be taken continuously for long periods of time.

Taking this medicine
- The tablets should be taken with water
- The tablets should not be broken, crushed or chewed.

How much to take
Adults and children over 12 years:
- The usual dose is two tablets 4 times a day
- For Irritable Bowel Syndrome, the doctor may give a lower starting dose of one tablet 3 times a day. This dose may be increased, if further relief is necessary.

Children 6 - 12 years:
- The usual dose is one tablet 3 times a day

Buscopan 10 mg Tablets are not recommended for children under 6 years.
For further information on how Buscopan 10 mg Tablets are used, please refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

**What benefits of Buscopan 10 mg Tablets have been shown in studies?**
The application for Buscopan 10 mg Tablets is considered to be identical to the previously authorised application for Buscopan Tablets/Cramps (PL 00015/0047R), with the same benefits and risks. So, no new studies have been provided for Buscopan 10 mg Tablets; however, reference is made to the studies for Buscopan Tablets/Cramps (PL 00015/0047R).

**What are the possible side effects from Buscopan 10 mg Tablets?**
Like all medicines, Buscopan 10 mg Tablets can cause side effects, although not everybody gets them. The following side effects may occur with this medicine. The patient should stop taking the medicine and see a doctor straight away if he/she notices any of the following serious side effects – the patient may need urgent medical treatment:

- Allergic reactions such as skin reactions e.g. nettle rash, itching (affects fewer than 1 in 100 people), rash, redness of the skin.
- Severe allergic reactions (anaphylactic shock) such as difficulty breathing, feeling faint or dizzy (shock).
- Painful red eye with loss of vision.

**Other side effects**
- Dry mouth (affects fewer than 1 in 100 people)
- Small blisters on hands and feet (affects fewer than 1 in 100 people)
- Increased heart rate (affects fewer than 1 in 100 people)
- Being unable to pass water (urine) (affects fewer than 1 in 1,000 people).

**Reporting of side effects**
If the patient experiences any side effects, he/she should talk to a doctor, pharmacist or nurse. This includes any possible side effects not listed above. Side effects can also be reported directly via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). The reporting of side effects can help provide more information on the safety of medicines.

For a full list of all the side effects reported with Buscopan 10 mg Tablets, see section 4 of the package leaflet available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

**Why are Buscopan 10 mg Tablets approved?**
No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Buscopan 10 mg Tablets outweigh the risks; and the grant of a Marketing Authorisation was recommended.

**What measures are being taken to ensure the safe and effective use of Buscopan 10 mg Tablets?**
Safety information has been included in the Summary of Product Characteristics and the package leaflet for Buscopan 10 mg Tablets, 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/reviewed continuously as well.

**Other information about Buscopan 10 mg Tablets**
A Marketing Authorisation was granted in the UK to Boehringer Ingelheim Limited on 10 October 2014.
The full PAR for Buscopan 10 mg Tablets follows this summary.

For more information about treatment with Buscopan 10 mg Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in December 2014.
Buscopan 10 mg Tablets
(hyoscine butylbromide)

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Boehringer Ingelheim Limited a Marketing Authorisation for the medicinal product Buscopan 10 mg Tablets (PL 00015/0347) on 10 October 2014. The product is a prescription-only medicine (POM) 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 application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Buscopan Tablets/Cramps (PL 00015/0047R), which were granted a Marketing Authorisation to Boehringer Ingelheim Limited on 23 April 1985.

Buscopan 10 mg Tablets contain the active ingredient, 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 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.

No new data were submitted nor were data necessary for this simple application, as the data are identical to those of the previously granted cross-reference product.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00015/0347
PROPRIETARY NAME(S): Buscopan 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: POM

1. INTRODUCTION
This is an abridged application for Buscopan 10 mg Tablets submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Buscopan Tablets/Cramps (PL 00015/0047R) which were granted a licence in the UK to Boehringer Ingelheim Limited on 23 April 1985. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name
The proposed name of the product is Buscopan 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 10 mg hyoscine butylbromide.

The finished product is packaged in blisters, in pack sizes of 56, 100, 500 and 560 tablets.

Not all pack sizes may be marketed.

The proposed shelf life for the product is 5 years. Buscopan 10 mg Tablets should be protected from light and stored in a dry place below 25°C.

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

2.3 Legal status
On approval, the product will be available as a prescription-only medicine (POM) medicine.

2.4 Marketing Authorisation Holder/Contact Persons/Company
Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

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
With the exception of beeswax, none of the excipients contain materials of animal or human origin. The supplier of beeswax white has provided a declaration to confirm compliance with current European guidelines concerning the minimising of risk of transmission of Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathies (BSE/TSE). This is consistent with the cross-reference product.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application, because the proposed product is manufactured to the same formula and utilises the same processes as the reference product Buscopan Tablets/Cramps (PL 00015/0047R).

3. EXPERT REPORTS
The applicant cross-refers to the data for Buscopan Tablets/Cramps (PL 00015/0047R) to which this application is claimed to be identical. This is acceptable.

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

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
PIL
The Patient Information Leaflet has been prepared in line with the details registered for the cross-reference product.

Boehringer Ingelheim Limited has previously submitted results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended, for Buscopan Tablets (PL 00015/0047R). The results indicate that the leaflet is well-structured and organised, easy to understand, and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

User-testing of the PIL for Buscopan 10 mg Tablets (PL 00015/0347) has been accepted based on the bridging report provided by the applicant making reference to the successful user-testing of the PIL for Buscopan Tablets (PL 00015/0047R) as the ‘parent PIL’.
Carton and label
The proposed artwork is consistent with the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the names of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSION
The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

Suitable justification has been provided for non-submission of an Environment Risk Assessment (ERA). As this product is intended for substitution with a product that is already marketed, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

No Risk Management Plan has been submitted and none was required. This application was received prior to 21 July 2012, the date from which pharmacovigilance regulations in accordance with Directive 2010/84/EU came into force. As the application is for substitution of an already authorised product, for which safety concerns requiring additional risk minimisation have not been identified, there is no need for a detailed European Risk Management Plan and the routine pharmacovigilance activities are sufficient. The reference product has been in use for many years and the safety profile of the active ingredient is well-established.

The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for this application is consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

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

EFFICACY
The application is identical to the previously granted application for Buscopan Tablets/Cramps (PL 00015/0047R). No new clinical pharmacology/efficacy data have been submitted with this application and none are required for this type of application.

SAFETY
No new safety data were supplied or required for this application. Hyoscine butylbromide has a well-established safety profile. No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE
The SmPC and PIL are satisfactory, and consistent with those for the cross-reference product. The labelling complies with statutory requirements and is satisfactory.

BENEFIT/RISK ASSESSMENT
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. Extensive clinical experience with hyoscine butylbromide is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is, therefore, considered to be positive.
Buscopan 10 mg Tablets
(hyoscine butylbromide)

PL 00015/0347

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 28 February 2012.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 04 May 2012.
3. Following assessment of the application the MHRA requested further information relating to the dossier on 09 August 2012, 23 January 2013, 23 April 2013, 28 August 2013 and 11 September 2014.
4. The applicant responded to the MHRA’s request, providing further information on the 28 September 2012, 22 March 2013, 26 July 2013, 22 May 2014 and 11 September 2014.
5. The application was granted on 10 October 2014.
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
Each tablet contains hyoscine butylbromide 10 mg as the active ingredient. The tablets also contain soluble starch, maize starch and sucrose.

To be taken by mouth as directed by the prescriber.

Please read the enclosed leaflet for further information.

Store in a dry place below 25°C. Protect from light.

Keep out of the sight and reach of children.

Attach dispensing label here.