Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Pharmacy to General Sales List Reclassification

Buscopan IBS Relief

Hyoscine Butylbromide 10mg

PL 53886/0012 - 0003

OPELLA HEALTHCARE UK LIMITED

TABLE OF CONTENTS

Introduction	Page 2
Background	Page 2
Proposed Terms of Reclassification	Page 2
General Sales List Criterion	Page 3
Assessment of Suitability for General Sales List Availability	Page 3
Risk Management Plan	Page 5
Reasons for not seeking advice from the Commission on Human Medicines	Page 6
Conclusion	Page 6

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK Government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (https://yellowcard.mhra.gov.uk/).

Alternative format versions of this report are available on request from reclassification@mhra.gov.uk

1 Introduction

Buscopan IBS Relief can be used in adults and children aged 12 years and over for the relief of gastro-intestinal tract spasm associated with medically confirmed irritable bowel syndrome (IBS).

Each tablet contains 10 milligrams (mg) of hyoscine butylbromide.

The licence holder[1], Opella Healthcare UK Limited, applied to make a pack size of 60 tablets of Buscopan IBS Relief available as a General Sales List medicine for sale through general retail outlets (see Background for definition).

The Medicines and Healthcare Products Regulatory Agency (MHRA) considers this product sufficiently safe to be sold on general sale. This report outlines the evidence that the MHRA reviewed and which led to the decision to approve the application.

2 Background

Buscopan IBS Relief relieves the abdominal cramps which cause pain and discomfort associated with IBS. It belongs to a group of medicines called antispasmodics. It works by relaxing the cramping muscles of your bowel.

Pharmacy medicines can be supplied without prescription only from pharmacies, by or under the supervision of a pharmacist. General Sales List medicines can be sold or supplied in other retail outlets other than pharmacies by someone who is not a pharmacist.

Hyoscine butylbromide 10mg tablets have been available on the UK market with General Sales List legal classification since 2004 with a pack size of 24 tablets. In 2014, a larger pack size (40 tablets) was approved as a General Sales List medicine.

Like the other pack sizes, the 60 tablet pack size of Buscopan IBS Relief can be used in adults and children aged 12 years and over for the relief of gastro-intestinal tract spasm associated with medically confirmed irritable bowel syndrome (IBS).

3 Proposed Terms of Reclassification

Opella Healthcare UK Limited proposed to make Buscopan IBS Relief available through general retail outlets with the following terms of reclassification:

a) Maximum pack size: 60 tablets
b) Used for the relief of gastrointestinal tract spasm associated with medically confirmed irritable bowel syndrome (IBS) in adults and children aged 12 years and over
c) Maximum dose: 20mg (2 tablets)
d) Maximum daily dose: 80mg (8 tablets)
e) Maximum strength: 10mg
f) Route of administration: For oral use

[1] A licence holder or marketing authorisation holder is the company with legal authorisation to make the medicine available to patients.

4 General Sales List Criterion

Under the provisions of The Human Medicines Regulations 2012, regulation 62(5), General Sales List is appropriate for medicines that can, with reasonable safety, be sold or supplied by someone other than a pharmacist.

The term “with reasonable safety” has been defined as: “where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser."

5 Assessment of suitability for General Sales List availability

The MHRA assessed the application against the General Sales List criterion, as stated in section 4.

5.1 Hazard to health

5.1.1 Safety profile

The post-marketing data[2] demonstrate that there has been no change in safety since the last increase in pack size as a GSL medicine in 2014. The MHRA accepts that a larger pack size is unlikely to increase the risk of side effects.

5.1.2 Pack size

The approved pack size of 60 tablets would allow Buscopan IBS Relief to be taken for 20 days if used at the minimum dose (one tablet taken three times a day), and 7 days if used at the maximum dose (two tablets taken four times a day). The maximum recommended duration of use of the medicine is 2 weeks, therefore there is a small risk of some patients using the medicine continuously for longer than 2 weeks with a pack size of 60 tablets. A potential risk of continued use of the medicine beyond 2 weeks may include a delay in diagnosing an underlying condition, however this risk is not considered to outweigh the benefit of the increased pack size (see section 5.4). Buscopan IBS Relief is only indicated for individuals who have an established diagnosis of IBS. Therefore, the onset of symptoms such as abdominal pain or cramping is likely to be familiar and is unlikely to be mistaken for an underlying condition.

Furthermore, other possible conditions with similar symptoms often present with additional symptoms, therefore the risk of missing an alternative condition is considered to be low.

To manage the potential risk of continuous use, a warning has been included on the carton which advises for medical advice to be sought if symptoms persist after 2 weeks.

The availability of Buscopan IBS Relief in a pack size of 60 tablets may exceed the maximum recommended duration of use in some patients, however this would not set a precedent as there are other GSL products used to relieve the symptoms of IBS which also exceed the recommended duration of use before seeking advice from a doctor.

[2] Post-marketing data estimates how many people have taken a medicine and how many side effects have been reported after it has been released onto the market.

5.2 Risk of Misuse

There are no issues related to the risk of misuse of this medicine as a GSL medicine, therefore the availability of a 60 tablet pack size does not increase this risk.

The risk of unintentional misuse in other conditions is managed both by the need for an established medical diagnosis before use, and the current warnings related to duration of continuous use and the emergence of new symptoms.

5.3 Special Precautions in Handling

There are no special precautions required in handling Buscopan IBS Relief in a pack size of 60 tablets.

5.4 Wider sale would be a convenience

The MHRA accepts that a larger pack size would allow multiple episodes to be treated. An 'episode' of IBS refers to a group of symptoms occurring together, including repeated pain in the abdomen, cramping, bloating, and changes in the bowel movements, which may be diarrhoea, constipation, or both. Considering the episodic nature of IBS, this benefit is considered to be relevant and outweighs the small risks associated with continuous use of the product beyond 2 weeks.

6 Risk Management Plan

There are no changes proposed to the Risk Management Plan (RMP) as part of this application. RMPs are documents that contain information on a medicine's safety profile and one or more of the following:

- how any risks identified in the safety profile will be prevented or minimised in patients
- plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine
- risk factors for side effects
- measuring the effectiveness of measures taken to prevent or minimise risks.

The normal practices to monitor the safety of Buscopan IBS Relief are considered sufficient to address the important identified risks. The identified risks will be managed using routine risk minimisation measures, such as the clear advice in the product information (Summary of Product Characteristics, labelling and patient information leaflet) on how to use the product safely and correctly. No additional measures were proposed as part of this application.

7 Reasons for not seeking advice from the Commission on Human Medicines[3]

No major issues have been identified in the assessment of this application. The availability of a 60 tablet pack size of Buscopan IBS Relief as a General Sales List medicine would result in minimal changes based on the following reasons:

[3] The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. Their views are sought on reclassifications when more complex or new reclassifications of medicines are being proposed.

1. The proposed indication, posology, route of administration, strength and duration of treatment are as per the currently approved pack sizes on this licence.
2. There are no safety concerns associated with this increase in pack size.
3. There are other GSL products available for the relief of IBS symptoms which are available in even larger pack sizes (100 capsules).
4. The label has been updated to include a warning about seeking medical advice if symptoms persist for longer than 2 weeks.

8 Conclusion

The MHRA has taken the decision to approve General Sales List legal status for a 60 tablet pack size of Buscopan IBS Relief under the following conditions:

a) Maximum pack size: 60 tablets
b) Used for the relief of gastrointestinal tract spasm associated with medically confirmed irritable bowel syndrome (IBS) in adults and children aged 12 years and over
c) Maximum dose: 20mg (2 tablets)
d) Maximum daily dose: 80mg (8 tablets)
e) Maximum strength: 10mg
f) Route of administration: For oral use

Medicines and Healthcare products Regulatory Agency,
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