

IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR Buscopan® 10mg tablets and baclofen 10mg tablets

SUMMARY OF ASSESSMENT AND ITS FINDINGS

BACKGROUND

Numerous incidences have been reported of medication errors due to confusion between Buscopan® 10mg tablets (hyoscine butylbromide) and baclofen 10mg tablets. The majority of errors occurred whilst dispensing although some have occurred whilst prescribing or administering. Though reports indicated low or no harm to the patients already affected, the potential consequences range from patients being given a medicine that is ineffective for their condition or adverse reactions to a medicine that they were not prescribed. Risk assessment is therefore undertaken in order to explore whether the products' presentation contributes to this issue.

DETAILS OF PRODUCT (S) ASSESSED

- Buscopan® (hyoscine butylbromide) 10mg tablets [POM]. Boehringer Ingelheim
- Buscopan® Cramps (hyoscine butylbromide) 10mg tablets [P]. Boehringer Ingelheim
- Buscopan® IBS Relief (hyoscine butylbromide) 10mg tablets [GSL]. Boehringer Ingelheim
- Baclofen 10mg tablets [POM].
- Generic brands by Actavis Pharmaceuticals, Mylan Pharmaceuticals, Almus Pharmaceuticals and Teva. Doncaster Pharmaceuticals, Copharma. Products by Doncaster pharmaceuticals and Copharma are not included in this assessment as pictures of product packaging; labels and information were not supplied.

CONCLUSION FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

Three key areas, related to products' presentation, were highlighted that might increase the risk of misappropriation:

A. Name of product

The principally used names of the two products (Buscopan® 10mg tablets and baclofen 10mg tablets) sound alike when spoken and look alike when read. This name is particularly important given that their strengths and form are the same (both being tablets of 10mg strength).

B. Layout and design of products

Judicious choice of layout, design and colour scheme of the outer and inner packaging is intended to aid healthcare professionals in selecting the correct product. Packaging for Buscopan® 10mg tablets and five generic versions of baclofen 10mg tablets were compared to assess whether there were any similarities in layout and design to Buscopan® that might have contributed to the risk. Use of a deep red, grey and white colour scheme by Actavis for their baclofen 10mg tablet outer pack contrasted well with the distinctive bright green and yellow colour scheme of Buscopan® making it a low risk choice of all the generic baclofen tablets available. However, there was very little to differentiate the foil blister inner packs of Buscopan® 10mg tablets and all brands of baclofen 10mg tablets.

C. Setting

In dispensaries that arrange products in alphabetical order by the principally used name, Buscopan® 10mg tablets and all brands of baclofen 10mg tablets are likely to be stored near to each other.

POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

Recommendations for the consideration of the manufacturer of Buscopan® 10mg tablets involve measures that increase the relative prominence of its generic name (hyoscine butylbromide) against the brand name. Such measures include reconsideration of their relative placement on the outer and inner pack, changes to font size, colour and style and displaying the generic name on at least three opposing sides, including an end and side of the outer pack. Specific changes to the design of text and font and choice of material for the inner foil pack of Buscopan® 10mg tablets are also suggested to diminish similarity between the inner packs of Buscopan® 10mg tablets and baclofen 10mg tablets.

Recommendations for the consideration of the manufacturer of baclofen 10mg tablets by Teva and Almus involve reconsideration of colour schemes to contrast better with the bright green and yellow colour scheme of Buscopan® 10mg tablets.

For healthcare professionals involved in purchasing; the outer packaging of the Actavis brand of baclofen 10mg tablets uses a deep red and grey colour scheme that contrasts most with the distinctive and well recognised green and yellow colour scheme for Buscopan® 10mg tablets. Currently, it may therefore be the choice that confers least risk.

Dispensary or pharmacy managers should be made aware of this issue and be advised to maintain separate stock locations for Buscopan® 10mg tablets and baclofen 10mg tablets. Shelf labels could be used to alert staff to the risk.

FULL ASSESSMENT REPORT

1. BACKGROUND

Numerous incidences have been reported of medication errors due to confusion between Buscopan® 10mg tablets (generic name hyoscine butylbromide) and baclofen 10mg tablets. The number of reports suggests a relatively high frequency of this occurring in practice. The errors often occurred during the dispensing process and occasionally at the prescribing or administration stages. Though the reports indicated low or no clinical harms to the patients already affected, the potential consequences range from consumers being given a medicine that is ineffective for their condition to adverse reactions to a medicine that they were not prescribed. This risk assessment is therefore undertaken in order to explore whether the products' presentation contributes to this risk of confusion between them.

2. THE PRODUCT (S)

- Buscopan® (hyoscine butylbromide) 10mg tablets [POM]. Boehringer Ingelheim
- Buscopan® Cramps (hyoscine butylbromide) 10mg tablets [P]. Boehringer Ingelheim
- Buscopan® IBS Relief (hyoscine butylbromide) 10mg tablets [GSL]. Boehringer Ingelheim
- Baclofen 10mg tablets [POM]. Actavis Pharmaceuticals.
- Baclofen 10mg tablets [POM]. Mylan Pharmaceuticals.
- Baclofen 10mg tablets [POM]. Almus Pharmaceuticals.
- Baclofen 10mg tablets [POM]. Teva
- Baclofen 10mg tablets [POM]. Doncaster Pharmaceuticals*.
- Baclofen 10mg tablets [POM]. Copharma*.

*not included in this assessment as pictures of product packaging, labels and information were not supplied.

3. ASSESSMENT FINDINGS

A. Name

The principally used names of the two products (Buscopan® 10mg tablets and baclofen 10mg tablets) differ only by three letters (bUScoPan® and baCLOfEn), beginning and ending with the same letters and having the same number of syllables. The result is that the names sound alike when spoken and can look alike when read on a screen or on paper. To add to this, the strength and form are exactly the same. These factors are thought to impact negatively on the risk of misappropriation and are it therefore important to consider implementation of steps that mitigate this risk.

B. Layout and design of products

The layout and design of the packaging is intended to aid healthcare professionals in selecting the correct product for their patients. Judicious use of colour plays an important role in this. The layout and design of the packaging for Buscopan® 10mg tablets and several generic versions of baclofen 10mg tablets were compared to assess whether there were any similarities that might have contributed to the risk of misappropriation. The following issues were highlighted using the UKMi risk assessment tool:

- The green and yellow colour scheme for Buscopan® 10mg tablets is quite distinctive and well recognised by pharmacy staff and possibly by patients and other healthcare professionals. However, the generic name, hyoscine butylbromide, only appears on the front and back of the pack. The sides and ends of the pack, which are most likely to be visible on the shelf, only contain the brand name.



Six different generic products for baclofen 10mg tablets were identified and four were available to assess using the UKMi risk assessment tool. Design and colour schemes for each were different and therefore carried variable risk of misappropriation:

- The product by Teva Pharmaceuticals features panels of a similar shade of green to the Buscopan® 10mg tablets and therefore carries risk of misappropriation.



- The product by Actavis Pharmaceuticals uses a colour scheme of deep red, white and grey which is very distinct from the green and yellow scheme of Buscopan® 10mg tablets. This product, of all the generic baclofen 10mg tablet packages, carries a reasonably low risk of misappropriation in its current form.



- The product by Almus Pharmaceuticals features a background of a similar shade of green to the Buscopan® 10mg tablets and therefore carries risk of misappropriation



- The product by Mylan features panels of a lighter shade of green compared with Buscopan® 10mg tablets and therefore may carry a small risk of misappropriation.



Pharmacies, wards, care homes and patients in their own homes might store medication without outer packaging, which in these cases are the foil blisters that hold the tablets. Hence layout, size, design and judicious use of colours and material apply to this inner packaging as well as the outer. The UKMi risk assessment tool highlighted that there is very little to differentiate the foil blister inner packs of Buscopan® 10mg tablets and all brands of baclofen 10mg tablets.

C. Setting

Reports found that many of the errors occurred during the dispensing process as a result of misappropriation though some occurred when prescribing or administering. The UKMi risk assessment tool highlighted that storage requirements for both products are similar and as such, they are likely to be stored in a dispensary near to each other in pharmacies or dispensaries that arrange products in alphabetical order by the principally used name.

4. CONCLUSIONS, RECOMMENDATIONS, AND THEIR BASIS

A. Name

To try and avoid the risk of confusion between Buscopan® 10mg tablets and baclofen 10mg tablets, we recommend that the generic name of Buscopan® 10mg tablets is made to be more prominent compared to the brand name. Risk assessment determined that currently, the generic name (hyoscine butylbromide) lacks prominence compared with the brand name on the outer and inner packaging as well as the Patient Information Leaflet (PIL). As well as lacking prominence on the outer packaging, the generic name appears on only two faces of the 6 available, both on opposing sides less likely to be visible to the operator, whereas the brand name appears on all three opposing sides.

On the inner packaging, a blister foil pack, the generic name lacks prominence compared with the brand name and it does not begin directly below the brand name as it is centred differently. The font size of the generic name always appears much smaller than font size of the brand name and there is no differentiation with respect to font style or colour.

Our specific **recommendations** (for the consideration of the manufacturer of Buscopan® 10mg tablets) in order to increase the relative prominence of its generic name (hyoscine butylbromide) seek to address the above issues:

- Reconsideration of the relative placement of brand and generic names
- Increase in the size of font used to display 'hyoscine butylbromide' so that its font is 100% the size of the font used to display 'Buscopan' on the inner and outer packs.
- Use of a different coloured font and style of text to display the brand and generic names on outer and inner pack where possible.
- Addition of the generic name to three opposing sides of the outer pack, including an end and side, so that every face displaying the brand name also displays the generic name.
- Use of the generic name, with equal prominence, throughout the PIL in addition to the brand name.

Increasing the prominence of the generic name should be approached with some degree of caution, however, because there is a small risk that confusion between Buscopan® (hyoscine butylbromide) and products that contain hyoscine hydrobromide could be introduced due to their similar names. However, the comparative level of risk of this being an issue is judged to be low because products that contain hyoscine hydrobromide in tablet form are marketed directly to the public for Travel Sickness (e.g. Kwells® or Joy-Rides®). Packaging for these Travel Sickness medicines appears very different to packaging for Buscopan® as the former are intended for self administration whilst the latter are for dispensing. Furthermore, medicines for Travel Sickness are stored in the counter areas of pharmacies in primary care and often not stocked at all in secondary care. Finally the strengths and doses are very different between Buscopan® and the travel sickness medicines so the risk of misappropriation by pharmacy staff, patients and ward staff are considered low. Therefore, implementation of the above changes to increase the prominence of the generic name is not expected to introduce additional risk.

An additional recommendation to reduce risk of misappropriation and medication error is to enhance awareness of this issue amongst pharmacy staff and other healthcare professionals. One way of doing this is to add this as a known issue to published lists of commonly confused drug names (e.g. <http://www.ismp.org/tools/confuseddrugnames.pdf> and <http://www.ccforspatientsafety.org/common/pdfs/fpdf/Presskit/PS-Solution1.pdf> . <http://www.who.int/medicines/services/inn/StemBook2009.pdf>)

B. Layout and design of products

A reasonably broad range of baclofen 10mg tablet packs are available as it is produced by six different manufacturers. The packaging design and use of colour are different for each generic and so this might lead to some unfamiliarity amongst pharmacy staff, other healthcare professionals and patients around what baclofen 10mg tablets typically look like. However, little can be suggested that would reduce the range of products available.

Our **recommendations** therefore focus on the layout, design and use of colour on the packaging of Buscopan® 10mg tablets and baclofen 10mg tablets:

- The distinctive and well recognised green and yellow colour scheme for Buscopan® 10mg tablets should be retained.
- Use of the Actavis (and possibly the Mylan) brands of baclofen 10mg tablets are likely to confer least risk of misappropriation compared to other brands as the colour schemes used on their packaging contrasts with the bright green and yellow colour scheme of Buscopan® .
- Manufacturers of the Teva and Almus brands are advised to reconsider the use of the green colour used on their packs of baclofen 10mg tablets and advised to consider using a contrasting colour scheme to the bright green and yellow colour scheme of Buscopan® .
- As well as increasing the prominence of the generic name of Buscopan® on the inner foil as suggested above, manufacturers of Buscopan® might consider displaying the name of the product and its particulars in larger and more distinctive font along the length of the foil blister pack rather than repeatedly over each foil blister pocket in order to diminish similarity between the inner packs of Buscopan® 10mg tablets and baclofen 10mg tablets.
- Manufacturers of Buscopan® might also consider use of distinctive coloured and/or non-reflective foil to further differentiate between inner packs of it and baclofen 10mg tablets.

C. Setting

Our **recommendations** on reducing risk of misappropriation that are relevant to the setting include:

- Medicines management leads should consider issuing a communication to prescribers, alerting them to this safety issue. In addition, they should consider whether prescribing systems used in primary and secondary care could be set to alert system users to it. For

example; if selecting 'Buscopan', users could be reminded that the generic name for Buscopan is hyoscine butylbromide and they could then be asked to confirm their choice. A similar alert could be in place when baclofen is selected; for example "safety alert – confusion with the 'Buscopan' brand of hyoscine butylbromide has been reported, please check and confirm your selection."

- Dispensary or pharmacy managers should be advised that there have been reported drug errors involving Buscopan® 10mg tablets and baclofen 10mg tablets due to misappropriation. They should be advised to cascade this information to their teams.
- Dispensary or pharmacy managers should be advised to maintain separate stock locations for Buscopan® 10mg tablets and baclofen 10mg tablets and store these two products alphabetically but according to their generic names. They should be advised to convey this change to their teams. Shelf labels could be used to alert staff to the risk.

Changing the stock location of Buscopan® according to its generic name might be approached with some degree of caution, however, because of the small risk of confusion between Buscopan® (hyoscine butylbromide) and products that contain hyoscine hydrobromide. However, for the reasons highlighted above, the comparative level of risk of this being an issue is judged to be low.

This report was produced by the London Medicines Information Service (LMIS) at Northwick Park Hospital and Trent Medicines Information at University Hospitals of Leicester using photographic images (not physical products) of licensed Buscopan® and four generic baclofen products that were available at the time of assessment. Images were obtained primarily from pharmaceutical companies, but also from the Commercial Medicines' Unit PharmaQC database (<http://cmu.dh.gov.uk/medicines/pharmaqc-database/>) and from various sources within the NHS.

This report summarises product assessments undertaken by:

- London Medicines Information Service (LMIS) at Northwick Park Hospital
- Trent Medicines Information at University Hospitals of Leicester

For comments email <nwlh-tr.medinfo@nhs.net>