Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Prescription Only Medicine to Pharmacy Reclassification

Calci-D 1000mg/1000 IU chewable tablets

Calcium & Cholecalciferol (Vitamin D3)

PL 24837/0075 - 0007

Consilient Health Limited

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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

Calci-D chewable tablets can be used for the correction of calcium and Vitamin D deficiency in the elderly. Calci-D may also be used as an adjunct to specific therapy for osteoporosis, in patients with either established vitamin D and calcium combined deficiencies or in those patients at high risk of needing such therapeutic supplements.

Each chewable tablet contains 2500mg calcium carbonate (equivalent to 1000mg calcium) and 1000 I.U. (equivalent to 0.025mg) cholecalciferol (Vitamin D3).

The licence holder[1], Consilient Health Limited, applied to change the legal status of this medicine from a Prescription Only Medicine (POM) to a Pharmacy (P) medicine (see Background for definition).

The Medicines and Healthcare products Regulatory Agency (MHRA) considers this product sufficiently safe to be sold as a pharmacy medicine. This report outlines the evidence that the MHRA reviewed and which led to the decision to approve the application.

2 Background

A Prescription Only Medicine (POM) must be prescribed by a doctor or other authorised health professional and it must be dispensed from a pharmacy or from another specifically licensed place.

Pharmacy medicines can be supplied without prescription only from pharmacies, by or under the supervision of a pharmacist.

Calci-D was first approved in 2015 as a prescription only medicine in the UK. There are already many products available as P medicines in the UK which contain calcium and vitamin D3. Currently the highest strength of Calcium available in a P only medicine is 1500mg, which is higher than the strength of calcium in this product. However, the maximum strength of Vitamin D3 in a calcium/Vitamin D3 product classified as P is 880IU. Therefore, this product is the first P medicine to contain 1000 IU of vitamin D3.

3 Proposed Terms of Reclassification

Consilient Health Limited proposed to make Calci-D chewable tablets available through pharmacies with the following terms of reclassification:

a) Pack size: 28 chewable tablets
b) For the correction of calcium and Vitamin D deficiency in the elderly. Calci-D may be used as an adjunct to specific therapy for osteoporosis, in patients with either established vitamin D and calcium combined deficiencies or in those patients at high risk of needing such therapeutic supplements.
c) Dose: Adults and elderly: One tablet daily
d) Route of administration: Oral use

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

e) Strength: Each chewable tablet contains 2500mg calcium carbonate (equivalent to 1000mg calcium) and 1000 I.U. (equivalent to 0.025mg) cholecalciferol (Vitamin D3).

4 Prescription Only Medicine (POM) Criteria

To be reclassified from POM to P, a medicine must:

- be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- be generally used correctly (i.e. not frequently or to a wide extent used correctly)
- not contain substances or preparations of substances where the activity of the product or its side effects require further investigation
- not normally be prescribed by a doctor for injection (parenteral administration)

These criteria are set out in the Human Medicines Regulations 2012, regulation 62(3).

5 Assessment of suitability for Pharmacy availability

The MHRA assessed the application against the POM criteria as stated in section 4.

5.1 POM Criteria 1

5.1.1 Direct Danger

'Direct danger' means that a danger may be present if the product causes adverse reactions that are important.

There are already a number of products containing calcium/vitamin D available as P medicines. However, Calci-D chewable tablets contain a higher strength of vitamin D compared to any others.

Therefore, the focus of this assessment against the POM criteria was the safety of Calci-D chewable tablets to provide reassurance that there is no direct danger to human health when used without the supervision of a doctor, even if used correctly (first POM criterion).

The safety profile of calcium/vitamin D supplements is well-established. The daily dose of vitamin D in the product is below what is considered to be the harmful dose according to the available literature. The daily dose of vitamin D provided with this product is only marginally more (3-5 mcg) than products which are currently available as P products. There is no evidence to suggest that this additional amount constitutes any additional risk. The total daily dose must also be considered in the context of other sources of Vitamin D, e.g. from other medicines and food, and patients with certain medical conditions who are more susceptible to the effects of vitamin D toxicity. However, this is managed by appropriate warnings in the product information.

The recommended maximum daily dose differs slightly depending on the source of information, but the European Food Safety Authority recommends 100mcg/day as the upper limit. Therefore, the amount of vitamin D in Calci-D chewable tablets (25mcg) is much lower than this upper limit. There is no evidence

to suggest that this additional amount constitutes any additional risk, and as such there is no direct danger associated with the use of this product without the supervision of a doctor.

5.1.2 Indirect Danger

"Indirect dangers" are considered to be when treatment might mask an underlying condition that requires medical attention.

There are already a number of products containing calcium/vitamin D available as P medicines, therefore the risk of supply of the product for a different diagnosis has already been considered. The availability of calci-D chewable tablets as P medicine which contains a slightly higher dose of vitamin D is not considered to increase the risk of indirect danger.

The maximum pack size of Calci-D chewable tablets (28 tablets) is also aligned with other vitamin D/calcium P medicines.

5.2 POM Criteria 2

5.2.1 Incorrect Use

There is no evidence that Calci-D chewable tablets is frequently and to a very wide extent used incorrectly.

5.3 POM Criteria 3

5.3.1 Activity and/or adverse reactions require further investigation

This medicinal product contains calcium and vitamin D as the active ingredients. The activity of and adverse reactions to these are well established and do not require further investigation. Furthermore, both calcium and vitamin D are already available as P medicines and also in food supplements.

5.4 POM Criteria 4

5.4.1 Is normally prescribed as an injection

This product is for oral use only, so this criterion does not apply.

6 Product Information

The label has been updated to reflect the requirements for a P product as set out in The Human Medicines Regulation 2012. In particular, the indications, full dosage instructions and relevant warnings for the medicine in language that will be understood by the patient have been included on the outer label.

The patient information leaflet has also been updated to ensure that the information is appropriate for a P medicine and aligns with the Quality Review of Documents (QRD) product information template.

7 Reasons for not seeking advice from the Commission on Human Medicines[2]

No major issues were identified in the assessment of this application. The availability of Calci-D chewable tablets as a Pharmacy medicine would result in minimal changes based on the following reasons:

- The increased amount of vitamin D is not expected to change the safety profile of the product
- There are a number of calcium/vitamin D licences already available as P medicines which have the same indications
- The product information aligns with the requirements for P classification identified for all calcium/vitamin products classified as P

8 Conclusion

The MHRA has taken the decision to approve Pharmacy legal status for Calci-D chewable tablets under the following conditions:

a) Pack size: 28 chewable tablets
b) For the correction of calcium and Vitamin D deficiency in the elderly. Calci-D may be used as an adjunct to specific therapy for osteoporosis, in patients with either established vitamin D and calcium combined deficiencies or in those patients at high risk of needing such therapeutic supplements.
c) Dose: Adults and elderly: One tablet daily
d) Route of administration: Oral use
e) Strength: Each chewable tablet contains 2500mg calcium carbonate (equivalent to 1000mg calcium) and 1000 I.U. (equivalent to 0.025mg) cholecalciferol (Vitamin D3).

Medicines and Healthcare products Regulatory Agency,
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[2] 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.