DULCOEASE 100MG CAPSULES
(docusate sodium)

PL 00015/0281

UKPAR

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Dulcoease 100mg capsules
(docusate sodium)

PL 00015/0281

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Boehringer Ingelheim Limited a Marketing Authorisation (licence) for the medicinal product, Dulcoease 100mg capsules (PL 00015/0281), on 6th October 2010. This is a medicine available on the General Sales List (GSL), and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Dulcoease 100mg capsules is a stool softener, which provides relief when bowel movement is painful or difficult. It can be used when you have constipation, piles or anal fissure. It works by helping hard, dry stools soak up natural fluids. It may also be used prior to abdominal x-ray.

This application is considered to be identical to a previously granted licence for Dioctyl Capsules / DulcoEase (PL 00039/0737), authorised to UCB Pharma Limited on 12th February 2008. The proposed and reference products are identical.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of Dulcoease 100mg capsules outweigh the risk; hence a Marketing Authorisation has been granted.

Dulcoease 100mg capsules
(docusate sodium)

PL 00015/0281

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Boehringer Ingelheim Limited a Marketing Authorisation for the medicinal product, Dulcoease 100mg capsules (PL 00015/0281), on 6th October 2010. The product is available on a General Sales Licence (GSL).

This is a simple, abridged, 'informed consent' application submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross-referencing the Marketing Authorisation for Dioctyl Capsules / DulcoEase (PL 00039/0737), licensed to UCB Pharma Limited. The cross-referenced product was originally licensed to Schwarz Pharma Limited (PL 04438/0032) in May 1993 and underwent a Change of Ownership (CoA) to the current UCB Pharma Limited licence on 12th February 2008.

Dulcoease 100mg capsules are used to prevent and treat chronic constipation, as follows:

(i) soften hard, dry stools in order to ease defaecation and reduce straining at stool;

(ii) in the presence of haemorrhoids and anal fissure, prevent hard, dry stools and reduce straining

Dulcoease 100mg capsules are also used as an adjunct in abdominal radiological procedures.

The active ingredient, docusate sodium, is an anionic wetting agent, which acts as a faecal softener by lowering the surface tension and allowing penetration of accumulated hard dry faeces by water and salts. Docusate sodium also possesses stimulant activity.

The pharmacovigilance system as described by the Marketing Authorisation Holder (MAH) fulfils the requirements and provides adequate evidence that the MAH has the services of a Qualified Person (QP) 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.

The Marketing Authorisation Holder has provided adequate justification for not submitting a Risk Management Plan (RMP) and Environmental Risk Assessment (ERA).

No new data were submitted, nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 00015/0281
PROPRIETARY NAME:	Dulcoease 100mg capsules
ACTIVE INGREDIENTS:	docusate sodium
COMPANY NAME:	Boehringer Ingelheim Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	GSL

1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Dulcoease 100mg capsules. The proposed Marketing Authorisation Holder (MAH) is Boehringer Ingelheim Limited.

The reference product is Dioctyl Capsules / DulcoEase (PL 00039/0737), authorised to UCB Pharma Limited on 12th February 2008. The proposed and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the product is Dulcoease 100mg capsules. The product has been named in line with current requirements and the product name is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Dulcoease 100mg capsules are presented as two-colour (opaque white and opaque yellow) soft, oval, gelatin capsules, with a clear, colourless liquid fill, for oral administration. Each capsule contains 100 mg of the active ingredient, docusate sodium. The capsules are licensed for marketing in the following containers (full details are provided in the SmPC):

i) Polyethylene / polypropylene containers - pack sizes: 30, 100 and 250 capsules

ii) polyvinylchloride (PVC) / polyvinylidene chloride (PVdC) / aluminium foil blister strips, packed into cardboard outer cartons - pack sizes: 10, 20, 30, 40, or 50 capsules

The MAH has stated that not all pack sizes may be marketed. The container closure systems and pack sizes are the same as those for the reference product.

The approved shelf-life (36 months for polyethylene / polypropylene containers, 18 months for blisters) and storage conditions ('Do not store above 25ºC. Store in the original package in order to protect from moisture') are identical to the details registered for the cross-reference product.

2.3 Legal status

The product is a GSL licensed medicine, available by supply through pharmacies, supermarkets and other retail outlets without the need for supervision by a pharmacist.

2.4 Marketing Authorisation Holder / Contact Persons / Company

The proposed Marketing Authorisation Holder is 'Boehringer Ingelheim Limited, Consumer Healthcare, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS, United Kingdom'.

The Qualified Person (QP) responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of 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 consistent 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

The only excipient used that contains material of animal or human origin is gelatin. Satisfactory documentation has been provided by the gelatin supplier stating that the gelatin they provide complies with the criteria described in the current version of the monograph 'Products with risk of transmitting agents of animal spongiform encephalopathies'. None of the excipients are sourced from genetically modified organisms.

3. EXPERT REPORT

A satisfactory quality overall summary has been prepared by an appropriately qualified expert. The CV of the expert was provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product (two-colour (opaque white and opaque yellow) soft, oval, gelatin capsules with a clear, colourless liquid fill) is identical to that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / LABELLING

PIL

No PIL has been provided. There is no package leaflet for this medicinal product as all relevant information has been included on the label.

Labelling

Dulcoease 100mg capsules are presented in a carton which is a label and leaflet; no package leaflet is included. The carton has been the subject of consultation with target groups and is accepted.

User testing has been accepted, based on a bridging report provided by the applicant making reference to the successful user-testing for the reference product, Dioctyl Capsules / DulcoEase (PL 00039/0737)). The text, content and layout of the proposed carton are essentially identical to the approved carton for the reference product. The bridging report is accepted.

Mock-ups of the labelling have been provided and are satisfactory. The approved 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 included the name of the product in Braille on the outer packaging.

7. CONCLUSIONS

The grounds for this application are considered adequate. A Marketing Authorisation was, therefore, granted.

NON-CLINICAL ASSESSMENT

This is a simple, abridged, 'informed consent' application made under Article 10(c) of EC Directive 2001/83 (as amended).

No new non-clinical data have been supplied with this application and none are required for an application of this type. A non-clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

CLINICAL ASSESSMENT

This is a simple, abridged, 'informed consent' application made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to the Marketing Authorisation for Dioctyl Capsules / DulcoEase (PL 00039/0737).

No new clinical data have been supplied with the application, and none are required for applications of this type. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.

OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY

The data for this application are 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

This application is considered identical to the previously granted licence for Dioctyl Capsules / DulcoEase (PL 00039/0737, UCB Pharma Limited).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC is satisfactory and consistent with the details registered for the cross-reference product.

No Patient Information Leaflet has been provided as the carton text includes all the relevant information that would be presented in the PIL. The information stated in the carton text is satisfactory and consistent with the SmPC.

User testing of the carton has been accepted, based on a bridging report provided by the applicant making reference to the successful user-testing for the reference product, Dioctyl Capsules / DulcoEase (PL 00039/0737)). The bridging report is accepted.

Mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. In line with current legislation, the name of the product in Braille appears on the outer packaging.

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. The benefit: risk ratio is considered to be positive.

Dulcoease 100mg capsules
(docusate sodium)

PL 00015/0281

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation application on 8th May 2009

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 8th June 2009

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 25th September 2009 and 22nd February 2010

4 The applicant responded to the MHRA's requests, providing further information for the quality sections on 3rd December 2009 and 17th May 2010 respectively

5 The application was determined on 6th October 2010

Dulcoease 100mg capsules
(docusate sodium)

PL 00015/0281

STEPS TAKEN AFTER AUTHORISATION

Not applicable

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Dulcoease 100mg capsules (PL 00015/0281) is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Dulcoease 100 mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Docusate sodium 100 mg.
For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft

A two colour (opaque white and opaque yellow) soft, oval, gelatin capsule with a clear, colourless liquid fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

a) To prevent and treat chronic constipation.

(i) to soften hard, dry stools in order to ease defaecation and reduce straining at stool; and

(ii) in the presence of haemorrhoids and anal fissure, to prevent hard, dry stools and reduce straining.

b) As an adjunct in abdominal radiological procedures.

4.2 Posology and method of administration

Route of administration: Oral use

Adults and elderly:
Up to 500 mg should be taken daily in divided doses. Treatment should be commenced with large doses, which should be decreased as the condition of the patient improves.

For use with barium meals:
400 mg to be taken with the meal.

Children under 12 years:
Not recommended.

4.3 Contraindications

These capsules should not be administered when abdominal pain, nausea, vomiting or intestinal obstruction is present.

This product should not be given to patients with a known hypersensitivity to docusate sodium or any of the components.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.4 Special warnings and precautions for use

Organic disorders should be excluded prior to the administration of any laxative.

The treatment of constipation with any medicinal product is only adjuvant to a healthy lifestyle and diet, for example:

- Increased intake of fluids and dietary fibre.
- Advice on appropriate physical activity

If laxatives are needed every day, or if there is persistent abdominal pain, consult your doctor.

Contains sorbitol: do not use this medicine if you are intolerant to small quantities of sugar (sorbitol, fructose).

Contains colouring E110 which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

These capsules should not be taken concurrently with mineral oil.

4.6 Pregnancy and lactation

There are no adequate data from the use of the drug in pregnant women. Animal studies are insufficient with respect to effects on pregnancy and embryonic foetal development. The potential risk for humans is unknown. During wide use, no adverse consequences have been reported.

Use in pregnancy only if the benefits outweigh the risks.

Docusate sodium is excreted in breast milk and should therefore, be used with caution in lactating mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely, these capsules can cause diarrhoea, nausea, abdominal cramps or skin rash.

4.9 Overdose

In rare cases of overdose, excessive loss of water and electrolytes should be treated by encouraging the patient to drink plenty of fluid. Electrolyte loss should be replenished where appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A06AA02 Laxatives, softeners, emollients

Docusate sodium is an anionic wetting agent, which acts as a faecal softener by lowering the surface tension and allowing penetration of accumulated hard dry faeces by water and salts.

Docusate sodium also possesses stimulant activity.

5.2 Pharmacokinetic properties

Docusate sodium exerts its clinical effect in the gastrointestinal tract. There is some evidence that docusate sodium is absorbed and is excreted in the bile. There is also evidence that docusate sodium is capable of enhancing absorption of certain compounds administered concomitantly

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

macrogol 400
propylene glycol
gelatin 195 bloom
purified water
sorbitol special (E420)
glycerol
titanium dioxide E171
quinoline yellow E104
sunset yellow E110

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

PVC/PVdC blister packs with aluminium foil: 18 months.

Polyethylene/polypropylene containers: 36 months.

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

PVC/PVdC blister packs with aluminium foil containing 10, 20, 30, 40, or 50 capsules.

Polyethylene / polypropylene containers, e.g.: securitainers / tampertainers containing 30, 100 and 250 capsules.

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Limited,
Consumer Healthcare,
Ellesfield Avenue,
Bracknell,
Berkshire RG12 8YS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00015/0281

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/10/2010

10 DATE OF REVISION OF THE TEXT

06/10/2010

LABELLING

Carton, including information for the patient

Blister foil