Safeguarding public health

MHRA

Public Assessment Report

Bayer Co-codamol 8/500mg Capsules
(codeine phosphate / paracetamol)

PL 00010/0372

Medicines and Healthcare products Regulatory Agency

BAYER CO-CODAMOL 8/500MG CAPSULES (CODEINE PHOSPHATE / PARACETAMOL) PL 00010/0372

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BAYER CO-CODAMOL 8/500MG CAPSULES (CODEINE PHOSPHATE / PARACETAMOL) PL 00010/0372

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Bayer plc a Marketing Authorisation (licence) for the medicinal product Bayer Co-codamol 8/500mg Capsules (PL 00010/0372) on 16 February 2006. This medicine is used for relieving painful and feverish conditions such as headaches, cold and flu symptoms, muscular and rheumatic pain, back pain, period pain and tooth pain. When the Marketing Authorisation was first granted for this product it was given Pharmacy (P) status, but on 1 May 2007 the status of this medicine was changed to Prescription Only Medicine (POM).

Bayer Co-codamol 8/500mg Capsules contains codeine phosphate, which relieves pain, and paracetamol, which relieves pain and fever.

This product was granted a Marketing Authorisation as a duplicate of Paracodol Capsules (PL 00031/0370). The Marketing Authorisation for Paracodol Capsules was transferred to Bayer plc (PL 00010/0339) on 7 October 2005.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Bayer Co-codamol 8/500mg Capsules outweigh the risks, hence a Marketing Authorisation has been granted.

BAYER CO-CODAMOL 8/500MG CAPSULES
(CODEINE PHOSPHATE / PARACETAMOL)
PL 00010/0372

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Bayer Co-codamol 8/500mg Capsules (PL 00010/0372) to Bayer plc on 16 February 2006.

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Paracodol Capsules (PL 00031/0370, approved on 30 June 1994). Paracodol Capsules are now licensed to Bayer plc under Marketing Authorisation number PL 00010/0339.

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

The product contains the active ingredients paracetamol and codeine phosphate. Codeine phosphate is an analgesic with uses similar to those of morphine, but only with mild sedative effects, and is much less liable than morphine to produce dependence or toxic effects. Paracetamol is well known for its analgesic and antipyetic actions.

Bayer Co-codamol 8/500mg Capsules is indicated for treatment of pain, including muscular and rheumatic pains, headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains, discomfort associated with influenza, feverishness, and feverish colds.

The assessment report that follows was written in response to PL 00031/0613 which was transferred to ***PL 00010/0372****.*

PHARMACEUTICAL ASSESSMENT

LICENCE Nos:	PL 00031/0613
PRODUCT NAME:	Co-codamol Capsules
COMPANY NAME:	Roche Products Ltd.
ACTIVES:	Paracetamol Ph.Eur.
	Codeine Phosphate Ph.Eur.
LEGAL STATUS:	P

Introduction

This is an abridged application made under Article 10.1a(i) of Directive 2001/83/EC for a product claimed to be identical to PL 00031/0370 for Paracodol Capsules, granted to Roche Products Ltd on 30 June 1994 when PL 00339/0043 was taken over.

Letters of access are not available but declarations have been given to confirm that the applicant has access to Parts II, III and IV data. The applicant has confirmed the existing site of manufacture but the finished product manufacturer has not provided a statement confirming that they are prepared to manufacture the product on the applicant's behalf. These omissions are considered acceptable as the applicant and cross-reference licence holder are the same.

Expert reports

Satisfactory Pharmaceutical, Pre-clinical and Clinical Expert statements are provided by suitably qualified experts.

Product name(s)

The product names are acceptable.

Marketing Authorisation Application (MAA) forms

Satisfactory MAA forms are provided.

TSE

Gelatin is an excipient of animal origin. Copies of current Ph.Eur. TSE Certificates for the gelatin used have been provided.

Additional data requirements

Satisfactory.

Summary of Product Characteristics (SPCs)

Satisfactory SPCs are provided.

Patient Information Leaflet (PIL)

Satisfactory.

LABELLING

Satisfactory.

CONCLUSION

A product licence may be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

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

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

This application is identical to a previously granted application for Paracodol Capsules.

No new or unexpected safety concerns arose from this application.

The SPC and combined PIL-labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-referenced product. Extensive clinical experience with the active ingredients codeine phosphate and paracetamol is considered to have demonstrated the therapeutic value of the compounds. The risk-benefit assessment is therefore considered to be favourable.

BAYER CO-CODAMOL 8/500MG CAPSULES
(CODEINE PHOSPHATE / PARACETAMOL)
PL 00010/0372

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Co-codamol 8/500mg Capsules on 3 September 2003.
2	The MHRA's assessment of the submitted data was completed on 26 September 2003.
3	Further information was requested from the company on 20 February 2004.
4	The applicant's response to further information was received on 29 March 2004 but certain replies were outstanding.
5	Additional information was requested from the company on 17 November 2004.
6	The applicant's response to additional information request was received on 9 December 2005.
7	The MHRA completed its assessment of the application on 13 December 2005.
8	The application was determined on 16 February 2006.

BAYER CO-CODAMOL 8/500MG CAPSULES
(CODEINE PHOSPHATE / PARACETAMOL)
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Variation type	Scope	Outcome
23/02/2006	II	To update section 4.9 (Overdose) of the SmPC in line with MHRA guidance.	Approved - 19/06/2006
21/11/2006	IB	To update section 6.5 (Nature and contents of container) of the SmPC by adding a 100 capsule pack size and concurrently removing all the other registered pack sizes. The pack size was implemented following approval the variation to change the legal basis of the medicine (see below).	Approved - 09/03/2007
21/11/2006	II	To change the legal status of the product from Pharmacy (P) to Prescription Only Medicine (POM). Associated changes have been made to sections 4.2, 4.4 and 4.8 of the SmPC. Consequential changes to the labelling and leaflet have been assessed and approved.	Approved - 01/05/2007
07/02/2008	II	To update section 4.8 (Undesirable effects) of the SmPC to include the side effect constipation.	Approved - 16/04/2008
19/09/2008	II	To update sections 4.4 (Special warnings and precautions for use) and 4.6 (Pregnancy and Lactation) of the SmPC to include information on the clinical safety of codeine.	Approved - 02/02/2011
16/10/2013	IB	To update sections 4.1 (Therapeutic indications), 4.2 (Posology and method of administration), 4.3 (Contraindications), 4.4 (Special warnings and	Approved - 04/11/2013

		precautions for use), 4.6 (Fertility, pregnancy and lactation) and 5.1 (Pharmacodynamic properties) of the SmPC to bring it in line with the PRAC recommendations regarding the use of codeine in children and in line with the UK statutory paracetamol warnings. Consequentially the label and leaflet have been updated.	

SUMMARY OF PRODUCT CHARACTERISTICS

The current approved UK version of the Summary of Product Characteristics (SmPC) for this product is available on the MHRA website.

PATIENT INFORMATION LEAFLET

The current approved UK version of the Patient Information Leaflet (PIL) for this product is available on the MHRA website.

LABELLING

The following is the approved label text for Bayer Co-Codamol 8/500 mg Capsules. Mock ups incorporating this text will be submitted to the MHRA for assessment.

Co-Codamol Caps Carton

Front of pack

Bayer
CO-CODAMOL
8 / 500 CAPSULES
Paracetamol (500mg) and
Codeine Phosphate (8mg)

100 Capsules

Flap 1

Manufactured by: Wrafton Laboratories Ltd, Wrafton, Braunton, Devon EX33 2DL for the Product Licence Holder: Bayer plc, Consumer Care Division, Newbury, Berkshire, RG14 1JA, UK.

Flap 2

Bayer
CO-CODAMOL
8 / 500 CAPSULES
Paracetamol (500mg) and
Codeine Phosphate (8mg)

Do not use after expiry date (EXP) on the side of the carton.
Do not store above 25°C.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
PL 00010/0372

POM

Back of pack

Bayer CO-CODAMOL 8/500mg CAPSULES are a combination of codeine, a painkiller, and paracetamol which relieves pain and reduces fever.

Bayer CO-CODAMOL 8/500mg CAPSULES provide strong relief from headaches (including tension headache and migraine), cold and flu symptoms including raised temperature and sore throats; muscular and rheumatic pain; back pain (including sciatica), neuralgia, period pain and dental pain.

Dosage:
Follow your doctor's instructions. Always read the leaflet.
Not recommended for children.

WARNING: Do not take more medicine than the label tells you to.
If you do not get better, talk to your doctor.

Contains paracetamol.
Do not take anything else containing paracetamol while taking this medicine.
Talk to a doctor at once if you take too much of this medicine, even if you feel well.

Do not take for longer than directed by your prescriber as taking codeine regularly for a long time can lead to addiction.

Each capsule contains: Active ingredients: Paracetamol 500mg and Codeine Phosphate 8mg.

Inactive ingredients: Pregelatinised Maize Starch, Colloidal Silicon Dioxide, Magnesium Stearate (E572), Gelatin, Shellac (E904), Titanium Dioxide (E171) and Red Iron Oxide (E172)