Safeguarding public health

MHRA

Public Assessment Report

Co-codamol 30mg/500mg Tablets
(codeine phosphate hemihydrate / paracetamol)

PL 22871/0001

Medicines and Healthcare products Regulatory Agency

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

UKPAR

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CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted koGEN Limited a Marketing Authorisation (licence) for the medicinal product Co-codamol 30mg/500mg Tablets (PL 22871/0001). This is a prescription only medicine (POM) for relieving severe pain.

Co-codamol 30mg/500mg Tablets contains codeine phosphate hemihydrate and paracetamol as active ingredients.

This application is a duplicate of a previously granted licence for Co-codamol 30/500 Tablets (PL 21590/0041).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Co-codamol 30mg/500mg Tablets outweigh the risks, hence a Marketing Authorisation has been granted.

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Co-codamol 30mg/500mg Tablets (PL 22871/0001) to koGEN Limited on 17 October 2006. The product is a prescription only medicine (POM).

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Co-codamol 30/500 Tablets (PL 21590/0041).

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 hemihydrate. Paracetamol has analgesic and antipyretic effects that do not differ significantly from that of aspirin. Its anti-inflammatory action is weak and it has practically no anti-platelet effect. The mechanism of action is unclear although it is believed to exert its action by inhibition of prostaglandin synthesis. Codeine is an analgesic with uses similar to those of morphine although it is much less potent as an analgesic and has only mild sedative effects. It is used for the relief of cough and pain. Codeine has a low affinity for opioid receptors, the analgesic effect of codeine may be due to its conversion to morphine; approximately 10% of administered codeine is demethylated to form morphine.

Co-codamol 30mg/500mg Tablets is indicated for the relief of severe pain.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	**PL 22871/0001**
PROPRIETARY NAME:	**Co-Codamol 30mg/500mg Tablets**
ACTIVE(S):	**Codeine phosphate hemihydrate** **Paracetamol**
COMPANY NAME:	**koGEN Limited**
E.C. ARTICLE:	**10.1(a)(i)**
LEGAL STATUS:	**POM**

INTRODUCTION

This is a simple national abridged Marketing Authorisation application for Co-Codamol 30mg/500mg Tablets containing paracetamol 500mg and codeine phosphate hemihydrate 30 mg as the active ingredients in a tablet for oral use. It cross-refers to an existing product on the UK market: Co-Codamol 30/500 Tablets/Kapake Tablets (PL 21590/0041, MA holder: Galen Limited) granted on 30 November 2004 as a change of ownership application from PL 20166/0041. PL 20166/0041 (granted 5 December 2003) was itself the result of a change of ownership application from PL 00440/0071, granted 3 March 1993.

Sandoz and Generics (UK) Limited have been included as own-label suppliers on this marketing authorisation.

The applicant has confirmed they are in possession of the Quality Module and that they have access to all data supplementary to the application. Confirmation has also been provided by the named manufacturer that they are prepared to manufacture the product on the applicant's behalf.

EXPERT REPORTS

Expert statements are provided, indicating that the proposed product is similar to the cross-reference product. The experts are suitably qualified.

ADDITIONAL DATA REQUIREMENTS

Details provided are generally identical to those of the cross-referenced product. It has been noted that the tablet markings have been changed and that this is an acceptable change.

SUMMARY OF PRODUCT CHARACTERISTICS
LABELLING
LEAFLET

Satisfactory.

PACKAGING

Confirmation was provided that the PVC/children-resistant aluminium blisters comply with BS8404. This packaging is consistent with the packaging listed for the reference product.

BSE/TSE Compliance

There are no TSE risks associated with this product.

CONCLUSION

Marketing Authorisation can 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 an application of this type.

EFFICACY

This application is identical to a previously granted application for Co-codamol 30/500 Tablets.

No new or unexpected safety concerns arose from this application.

The SPC, PIL and 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.

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Co-codamol 30mg/500mg Tablets on 21 June 2005.
2	Further information was requested from the company on 20 February 2006.
3	The applicant's response to further information was sent in a letter dated 5 May 2006.
4	Further information was requested from the company on 25 May 2006.
5	The applicant's response to further information request was sent in a letter dated 5 July 2006.
6	Additional information was requested from the applicant on 14 July 2006.
7	The applicant responded to additional information request on 15 July 2006 and 9 October 2006.
8	The MHRA completed its assessment of the application on 17 October 2006.
9	The application was determined on 17 October 2006.

CO-CODAMOL 30MG/500MG TABLETS
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Co-Codamol 30mg/500mg Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Per tablet
Paracetamol DC 96% PVP 4% (*Equivalent to 500mg Paracetamol)	520.830*mg
Codeine Phosphate Hemihydrate	30.000mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

Oblong, white uncoated tablets marked "K1" both sides of a scoreline on one side, the other side is plain and unmarked.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of severe pain.

4.2. Posology and method of administration

For oral administration.

Adults:
One to two tablets every four hours as required
Maximum of eight tablets daily.

Children:
Not recommended for children under 12 years of age.

Elderly:
The adult dose is appropriate.

4.3. Contraindications

Co-Codamol 30mg/500mg should not be used in patients hypersensitive to codeine phosphate hemihydrate, paracetamol or any of the other ingredients. It is contra-indicated in patients with raised intracranial pressure or head injury, respiratory depression, acute asthma and acute alcoholism. Co-Codamol 30mg/500mg is contra-indicated in patients receiving monoamine oxidase inhibitors or who have received these agents within the previous two weeks. It is not recommended for children under 12 years of age.

4.4. Special warnings and precautions for use

It should be used with caution in the elderly and debilitated as these patients may be more sensitive to the effects of opioids, those with prostatic hypertrophy, inflammatory or obstructive bowel disorders or Addison's disease. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Dependence of the morphine type may be produced especially with prolonged use of high doses of codeine.

Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed serious liver damage. Patients should be advised not to take other paracetamol-containing products concurrently.

Do not exceed the recommended dose. If symptoms persist, consult your doctor. Keep out of the reach of children.

4.5. Interaction with other medicinal products and other forms of interaction

The depressant effects of codeine may be enhanced by other central nervous system depressants : anxiolytics, hypnotics, antidepressants, antipsychotics and alcohol. If combined therapy is necessary, the dose of one or both agents should be reduced. Alcohol should be avoided.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6. Pregnancy and lactation

There is inadequate evidence for the safety of this combination product in pregnancy and lactation, therefore, it is not recommended in either instance.

4.7. Effects on ability to drive and use machines

Codeine may impair mental and/or physical abilities, therefore it may affect the ability to drive and operate machinery.

4.8. Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. The most common adverse effects to codeine are dizziness, drowsiness, nausea and vomiting. These effects are often more common in the ambulatory patient and thus may be alleviated if the patient lies down. Other side effects to codeine which may occur include constipation, urinary retention, light headedness, confusion, euphoria, dysphoria, miosis, bradycardia, abdominal pain, allergic reactions and pruritus.

4.9. Overdose

Paracetamol Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors

If the patient

(a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

or

(b) Regularly consumes ethanol in excess of recommended amounts.

or

(c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms of Paracetamol Overdose

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management of Paracetamol Overdose

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.
Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the National Poisons Information Service (NPIS) or a liver unit.

Codeine Overdose

The effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms of Codeine Overdose

Central nervous system depression, including respiratory depression, may develop but is unlikely to be severe unless other sedative agents have been co-ingested, including alcohol, or the overdose is very large. The pupils may be pin-point in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely.

Management of Codeine Overdose

This should include general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Consider activated charcoal if an adult presents within one hour of ingestion of more than 350mg or a child more than 5mg/kg.

Give naloxone if coma or respiratory depression is present. Naloxone is a competitive

antagonist and has a short half-life so large and repeated doses may be required in a seriously poisoned patient. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Natural opium alkaloids, ATC code: N02A A59.

Paracetamol has analgesic and antipyretic effects that do not differ significantly from that of aspirin. Its anti-inflammatory action is weak and it has practically no anti-platelet effect. The mechanism of action is unclear although it is believed to exert its action by inhibition of prostaglandin synthesis.
Codeine is an analgesic with uses similar to those of morphine although it is much less potent as an analgesic and has only mild sedative effects. It is used for the relief of cough and pain. Codeine has a low affinity for opioid receptors, the analgesic effect of codeine may be due to its conversion to morphine; approximately 10% of administered codeine is demethylated to form morphine.

5.2. Pharmacokinetic properties

Paracetamol is readily absorbed from the GI tract with peak plasma concentrations occurring about 30 minutes to two hours after oral administration. 90-100% of administered drug can be recovered in the urine within the first day. Practically none is excreted unchanged, most is conjugated in the liver with glucuronic acid or sulphuric acid.

Codeine and its salts are rapidly absorbed from the GI tract with peak plasma levels occurring about one hour after oral administration. Codeine is metabolised in the liver and excreted in the urine mainly as a conjugate of glucuronic acid. Approximately 10% of administered codeine is demethylated to form morphine.

Concurrent administration of both drugs does not interfere with the normal metabolic processes of each agent.

5.3. Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cellulose, Microcrystalline
Sodium Starch Glycolate (Type A)
Magnesium Stearate
Povidone

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 25°C. Store in the original package.

6.5. Nature and contents of container

PVC/child-resistant aluminium blisters.

Pack sizes: 2, 4, 6, 10, 20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 150, 200, 250 and 500 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

koGEN Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK.

8. MARKETING AUTHORISATION NUMBER

PL 22871/0001.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/10/2006

10 DATE OF REVISION OF THE TEXT

17/10/2006

Patient Information Leaflet

CO-CODAMOL 30mg/500mg TABLETS

(codeine phosphate hemihydrate and paracetamol)

PATIENT INFORMATION LEAFLET

This leaflet has been provided to help you understand about Co-Codamol 30mg/500mg Tablets and the way in which they should be taken to ensure you gain most benefit. Please read it carefully and follow the instructions given. If you have any questions, or are not sure about anything, ask your doctor or pharmacist's advice.

The Name of Your Medicine is CO-CODAMOL 30mg/500mg TABLETS

What are Co-Codamol 30mg/500mg Tablets?
Co-Codamol 30mg/500mg Tablets are one of a group of medicines called analgesics or painkillers. Each tablet contains 30mg of codeine phosphate hemihydrate and 500mg of paracetamol.

The other ingredients are microcrystalline cellulose, magnesium stearate, povidone and sodium starch glycolate.

This product is available in packs of 100 tablets.

Co-Codamol 30mg/500mg Tablets are oblong, white uncoated tablets marked "K1" both sides of a scoreline on one side, the other side is plain and unmarked.

The Marketing Authorisation holder for Co-Codamol 30mg/500mg Tablets is koGEN Limited, Seagoe Industrial Estate, Craigavon, BT63 5UA, UK. The tablets are manufactured by PDMS, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, UK.

What Do Co-Codamol 30mg/500mg Tablets Do?

This product is used to relieve severe pain.

Before Taking Your Medicine

You should NOT take Co-Codamol 30mg/500mg Tablets if you:

- Have ever had an allergic reaction to any of the ingredients listed above. (An allergic reaction can be a rash, itchiness or shortness of breath).
- Are suffering from head injuries.
- Have been told by your doctor that you suffer from respiratory depression.
- Are taking, or have taken in the last two weeks, medicine to relieve depression (Monoamine Oxidase Inhibitors/MAOIs). (If you are not sure of the types of medicines you are taking ask your doctor or pharmacist).
- Consume excessive amounts of alcohol on a regular basis.
- Are pregnant or breast-feeding.
- Suffer from severe but usually short-lasting asthma attacks.

Do **NOT** give this product to children under 12 years of age.

You should speak to your pharmacist or doctor before taking this product if you:

- Are elderly and/or in poor health.
- Suffer from an enlarged prostate.
- Suffer from any bowel problems.
- Suffer from Addison's disease.
- Suffer from any liver or kidney problems.
- Are taking any other medicines:
  - medicines for depression or anxiety or other medicines known as tranquillisers
  - medicines to help you sleep
  - cholestyramine (medicine for high cholesterol levels or diarrhoea)
  - domperidone or metoclopramide (medicines to stop you feeling sick or vomiting)
  - anticoagulants (medicine to prevent blood clots)
  - medicines that you have bought yourself such as cough/cold remedies or other painkillers. Many of these will contain paracetamol and/or codeine and should not be taken while you are taking Co-Codamol 30mg/500mg Tablets.

Note: Each tablet contains 1.2mg of sodium.

Other Warnings

You should avoid alcohol when taking this product.

Co-Codamol 30mg/500mg Tablets may make you feel drowsy. You should not drive or operate machinery until you know how they affect you.

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

Taking Your Medicine

How many should I take and how often?
Co-Codamol 30mg/500mg Tablets should be taken orally (by mouth).

For adults, the elderly and children over 12 years the usual dose is one or two tablets every four hours. You should not take more than two tablets at a time and not more than eight tablets in any 24 hour period.

Doctors sometimes prescribe different doses to this. Read the pharmacist's label, it will tell you exactly how many you should take.

Co-Codamol 30mg/500mg Tablets should not be given to children under 12 years.

You may find it hard to swallow the tablets whole. If this happens, they can be snapped along the breakline and each half taken with a drink of water.

What should I do if I forget to take a dose?
If you forget to take a dose, it may be because your symptoms have been relieved and you may not need to take Co-Codamol 30mg/500mg Tablets any more. However, if you still suffer from pain take your dose as soon as you remember and then carry on as before. It is important that you do not double the next dose.

What if too many tablets are taken?
It is always important to follow the dose recommended on the label. If too many tablets are taken, contact your doctor or hospital at once.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

After Taking Your Medicine

Are there any side-effects?

Along with its desirable effects a medicine may have unwanted effects.

This product may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down.

This product may cause an allergic reaction. An allergic reaction can be a skin rash, itching, swelling or shortness of breath. If you experience any of these please tell your doctor or pharmacist immediately.

There have been reports of low blood cell counts (platelets and white blood cells) associated with paracetamol-containing products, but these were not necessarily related to paracetamol. You may become aware of your heart beat slowing. You may also experience constipation, stomach pains, bladder problems, light headedness, narrowing of your pupils, confusion or changes in your mood while taking this product. Let your doctor know if this happens to you.

If you suffer from these or any other problems and think your medicine may be causing them, talk to your doctor or pharmacist.

Storing Your Medicine

How should I store Co-Codamol 30mg/500mg Tablets?

You should keep this product in a safe place out of the reach and sight of children. It should be stored below 25°C and kept in the original packaging in order to protect the tablets from moisture and light. This product should not be used after the expiry date shown on the carton and blister foil.

If your doctor tells you to stop taking Co-Codamol 30mg/500mg Tablets return any left over to the pharmacist. Only keep them if the doctor tells you to.

Remember - As with all medicines do **NOT** share with anyone else.

Date of Revision: 8 April 2006.

koGEN Limited
Seagoe Industrial Estate,
Craigavon,
BT63 5UA, UK PX553

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

pharma code
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SANDOZ

PATIENT INFORMATION LEAFLET SZ00000LT000

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(codeine phosphate hemihydrate and paracetamol)

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The tablets are manufactured by: PDMS, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, UK.
Distributed by: Sandoz Ltd, 37 Woolmer Way, Bordon, Hampshire, GU35 9QE, UK.

What Do Co-Codamol 30mg/500mg Tablets Do?

This product is used to relieve severe pain.

Before Taking Your Medicine

You should NOT take Co-Codamol 30mg/500mg Tablets if you:

- Have ever had an allergic reaction to any of the ingredients listed above. (An allergic reaction can be a rash, itchiness or shortness of breath).
- Are suffering from head injuries.
- Have been told by your doctor that you suffer from respiratory depression.
- Are taking, or have taken in the last two weeks, medicine to relieve depression (Monoamine Oxidase Inhibitors/MAOIs). (If you are not sure of the types of medicines you are taking ask your doctor or pharmacist).
- Consume excessive amounts of alcohol on a regular basis.
- Are pregnant or breast-feeding.
- Suffer from severe but usually short-lasting asthma attacks.

Do **NOT** give this product to children under 12 years of age.

You should speak to your pharmacist or doctor before taking this product if you:

- Are elderly and/or in poor health.
- Suffer from an enlarged prostate.
- Suffer from any bowel problems.
- Suffer from Addison's disease.
- Suffer from any liver or kidney problems.
- Are taking any other medicines:
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CO-CODAMOL 30MG/500MG TABLETS
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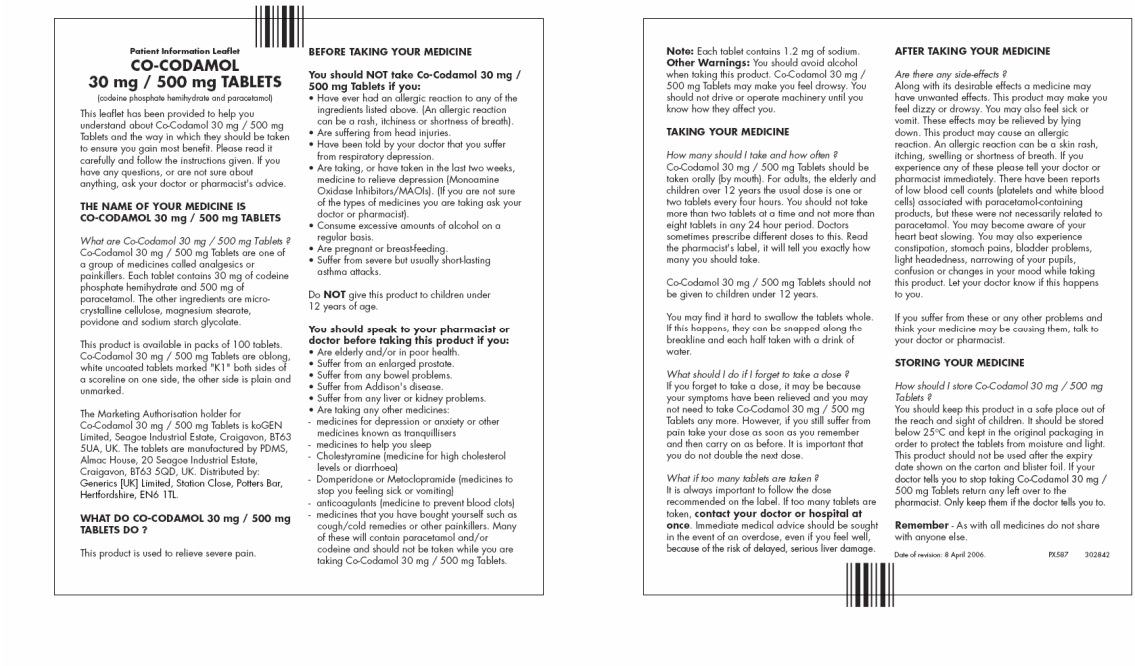

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CO-CODAMOL
30 mg / 500 mg TABLETS

(codeine phosphate hemihydrate and paracetamol)

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What are Co-Codamol 30 mg / 500 mg Tablets ?
Co-Codamol 30 mg / 500 mg Tablets are one of a group of medicines called analgesics or painkillers. Each tablet contains 30 mg of codeine phosphate hemihydrate and 500 mg of paracetamol. The other ingredients are micro-crystalline cellulose, magnesium stearate, povidone and sodium starch glycolate.

This product is available in packs of 100 tablets. Co-Codamol 30 mg / 500 mg Tablets are oblong, white uncoated tablets marked "K1" both sides of a scoreline on one side, the other side is plain and unmarked.

The Marketing Authorisation holder for Co-Codamol 30 mg / 500 mg Tablets is koGEN Limited, Seagoe Industrial Estate, Craigavon, BT63 5UA, UK. The tablets are manufactured by PDMS, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, UK. Distributed by: Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL.

WHAT DO CO-CODAMOL 30 mg / 500 mg TABLETS DO ?

This product is used to relieve severe pain.

BEFORE TAKING YOUR MEDICINE

You should NOT take Co-Codamol 30 mg / 500 mg Tablets if you:
- Have ever had an allergic reaction to any of the ingredients listed above. (An allergic reaction can be a rash, itchiness or shortness of breath).
- Are suffering from head injuries.
- Have been told by your doctor that you suffer from respiratory depression.
- Are taking, or have taken in the last two weeks, medicine to relieve depression (Monoamine Oxidase Inhibitors/MAOIs). (If you are not sure of the types of medicines you are taking ask your doctor or pharmacist).
- Consume excessive amounts of alcohol on a regular basis.
- Are pregnant or breast-feeding.
- Suffer from severe but usually short-lasting asthma attacks.

Do **NOT** give this product to children under 12 years of age.

You should speak to your pharmacist or doctor before taking this product if you:
- Are elderly and/or in poor health.
- Suffer from an enlarged prostate.
- Suffer from any bowel problems.
- Suffer from Addison's disease.
- Suffer from any liver or kidney problems.
- Are taking any other medicines:

- medicines for depression or anxiety or other medicines known as tranquillisers
- medicines to help you sleep
- Cholestyramine (medicine for high cholesterol levels or diarrhoea)
- Domperidone or Metoclopramide (medicines to stop you feeling sick or vomiting)
- anticoagulants (medicine to prevent blood clots)
- medicines that you have bought yourself such as cough/cold remedies or other painkillers. Many of these will contain paracetamol and/or codeine and should not be taken while you are taking Co-Codamol 30 mg / 500 mg Tablets.

Note: Each tablet contains 1.2 mg of sodium.
Other Warnings: You should avoid alcohol when taking this product. Co-Codamol 30 mg / 500 mg Tablets may make you feel drowsy. You should not drive or operate machinery until you know how they affect you.

TAKING YOUR MEDICINE

How many should I take and how often ?
Co-Codamol 30 mg / 500 mg Tablets should be taken orally (by mouth). For adults, the elderly and children over 12 years the usual dose is one or two tablets every four hours. You should not take more than two tablets at a time and not more than eight tablets in any 24 hour period. Doctors sometimes prescribe different doses to this. Read the pharmacist's label, it will tell you exactly how many you should take.

Co-Codamol 30 mg / 500 mg Tablets should not be given to children under 12 years.

You may find it hard to swallow the tablets whole. If this happens, they can be snapped along the breakline and each half taken with a drink of water.

What should I do if I forget to take a dose ?
If you forget to take a dose, it may be because your symptoms have been relieved and you may not need to take Co-Codamol 30 mg / 500 mg Tablets any more. However, if you still suffer from pain take your dose as soon as you remember and then carry on as before. It is important that you do not double the next dose.

What if too many tablets are taken ?
It is always important to follow the dose recommended on the label. If too many tablets are taken, **contact your doctor or hospital at once**. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

AFTER TAKING YOUR MEDICINE

Are there any side-effects ?
Along with its desirable effects a medicine may have unwanted effects. This product may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down. This product may cause an allergic reaction. An allergic reaction can be a skin rash, itching, swelling or shortness of breath. If you experience any of these please tell your doctor or pharmacist immediately. There have been reports of low blood cell counts (platelets and white blood cells) associated with paracetamol-containing products, but these were not necessarily related to paracetamol. You may become aware of your heart beat slowing. You may also experience constipation, stomach pains, bladder problems, light headedness, narrowing of your pupils, confusion or changes in your mood while taking this product. Let your doctor know if this happens to you.

If you suffer from these or any other problems and think your medicine may be causing them, talk to your doctor or pharmacist.

STORING YOUR MEDICINE

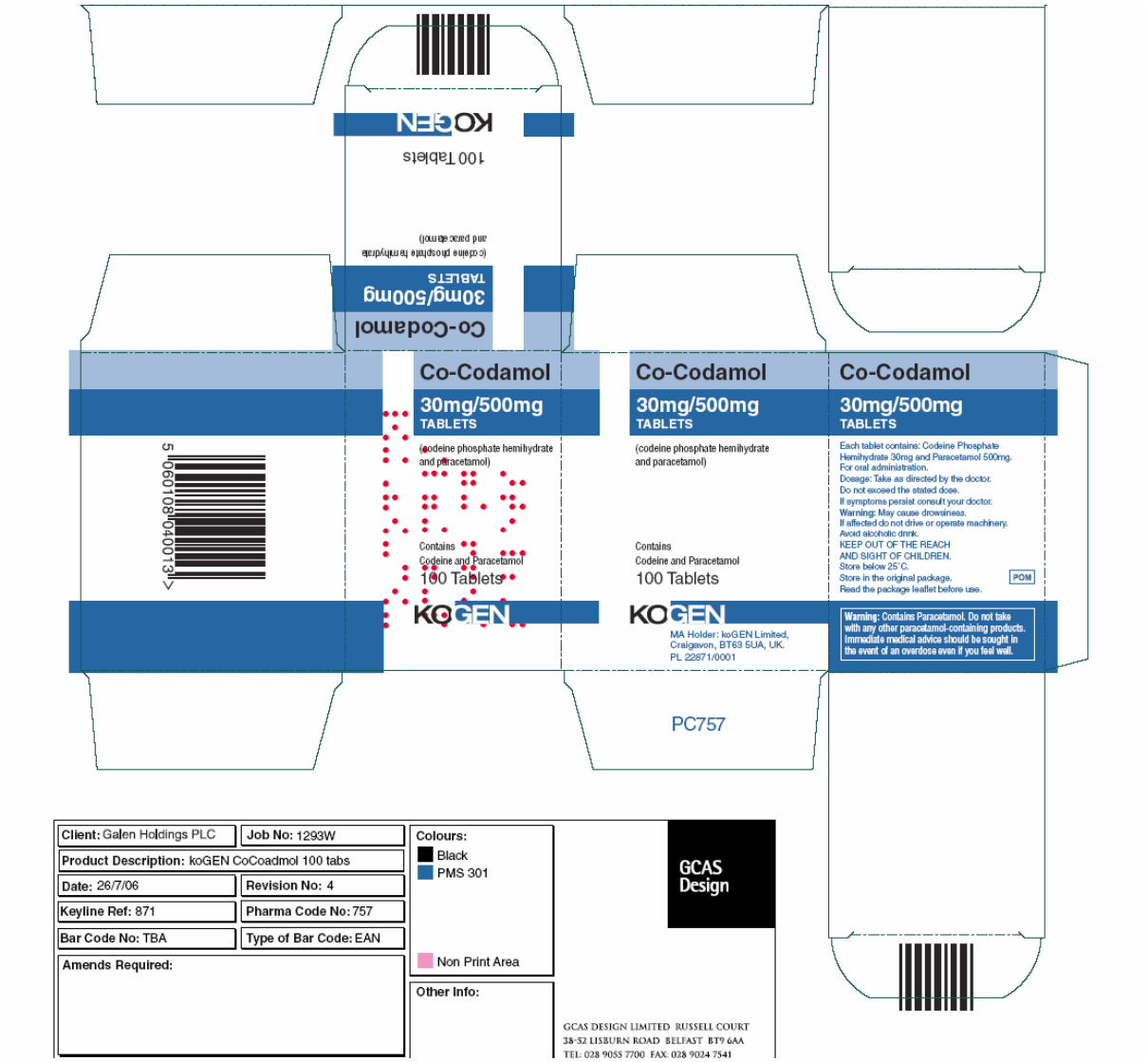
How should I store Co-Codamol 30 mg / 500 mg Tablets ?
You should keep this product in a safe place out of the reach and sight of children. It should be stored below 25°C and kept in the original packaging in order to protect the tablets from moisture and light. This product should not be used after the expiry date shown on the carton and blister foil. If your doctor tells you to stop taking Co-Codamol 30 mg / 500 mg Tablets return any left over to the pharmacist. Only keep them if the doctor tells you to.

Remember - As with all medicines do not share with anyone else.

Date of revision: 8 April 2006. PX587 302842

Labelling

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001



Client: Galen Holdings PLC	Job No: 1293W
Product Description: koGEN CoCoadmol 100 tabs	
Date: 26/7/06	Revision No: 4
Keyline Ref: 871	Pharma Code No: 757
Bar Code No: TBA	Type of Bar Code: EAN
Amends Required:	

Colours:
Black
PMS 301
Non Print Area

Other Info:

GCAS Design

GCAS DESIGN LIMITED RUSSELL COURT
38-52 LISBURN ROAD BELFAST BT9 6AA
TEL: 028 9055 7700 FAX: 028 9024 7541

CO-CODAMOL 30MG/500MG TABLETS
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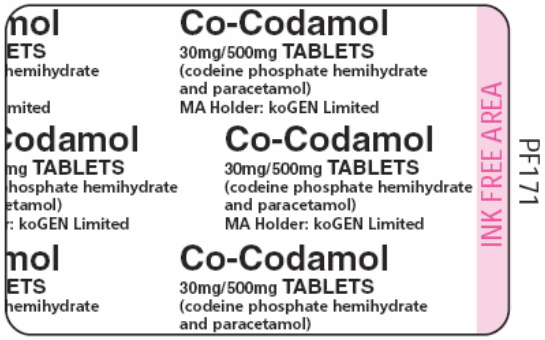
PL 22871/0001



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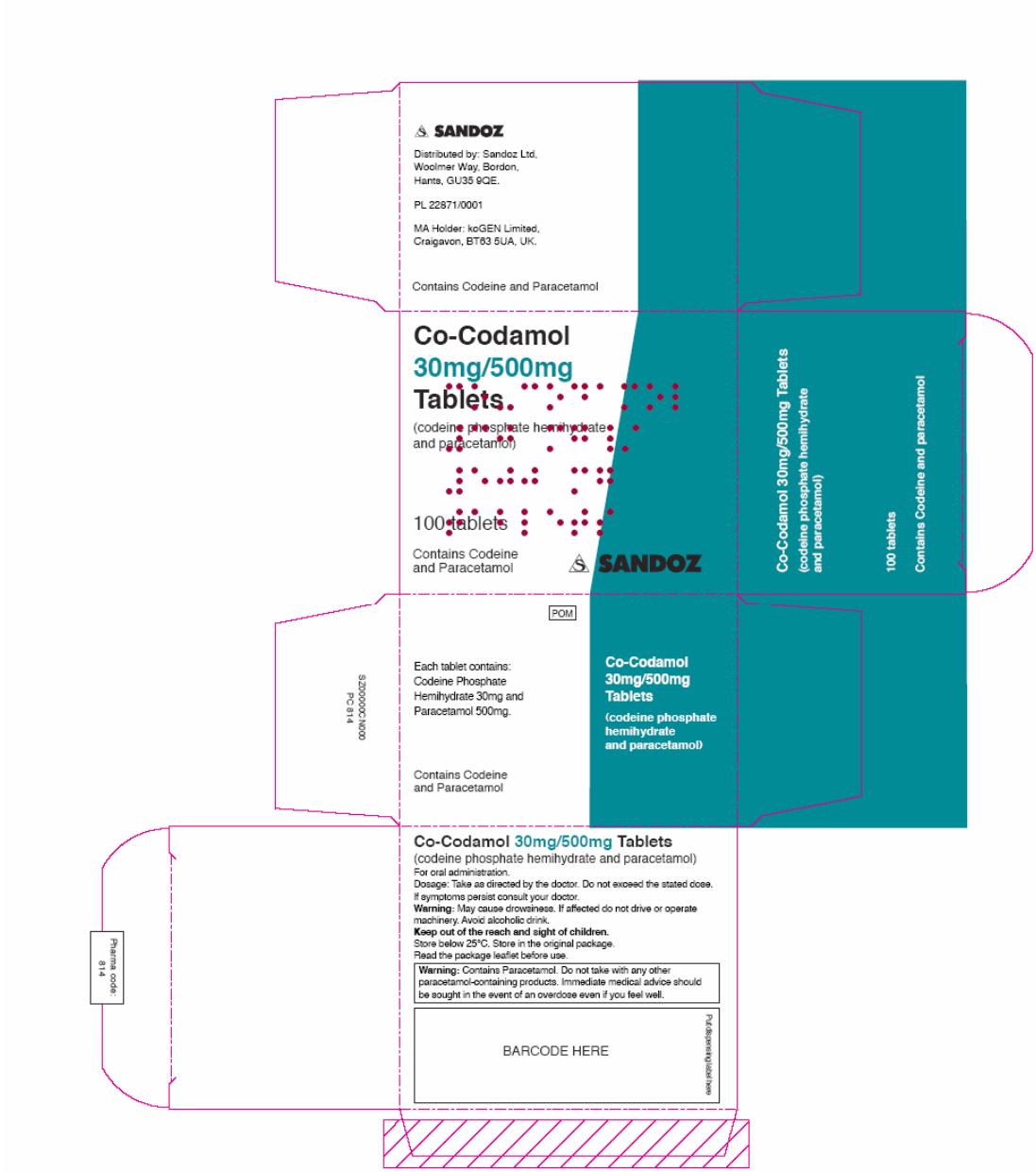

CO-CODAMOL 30MG/500MG TABLETS
(CODEINE PHOSPHATE HEMIHYDRATE / PARACETAMOL)
PL 22871/0001

PF178

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