CO-CODAMOL 30 / 500 MG EFFERVESCENT TABLETS

(codeine phosphate hemihydrate, paracetamol)

PL 24837/0004

UKPAR

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Consilient Health Limited a Marketing Authorisation (licence) for the medicinal product Co-codamol 30/500mg effervescent tablets (PL 24387/0004) on 3rd November 2008. This is a prescription-only medicine (POM).

Co-codamol 30/500mg effervescent tablets contain two active ingredients – paracetamol and codeine both of which belong to a group of medicines called pain-killers (analgesics). Co-codamol effervescent tablets are a 'compound analgesic' and are used to provide relief from severe pain.

This application is a duplicate of a previously granted application for Co-codamol effervescent tablets 30/500mg (PL 25099/0028), held by Zanza Laboratories Limited. The test and reference products are identical.

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

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(codeine phosphate hemihydrate, paracetamol)

PL 24837/0004

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Consilient Health Limited a Marketing Authorisation for the medicinal product Co-codamol 30/500mg effervescent tablets (PL 24387/0004) on 3rd November 2008. The product is a prescription-only medicine (POM).

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Co-codamol effervescent tablets 30/500mg (PL 25099/0028, Zanza Laboratories Limited), originally authorised to Zanza Healthcare Limited (as PL 15582/0022) on 7th March 2006.

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. A Public Assessment Report is also available for the cross-reference product; Co-codamol effervescent tablets 30/500mg (as PL 15582/0022).

Co-codamol 30/500mg effervescent tablets contain two active ingredients – paracetamol and codeine. Paracetamol is an analgesic which acts peripherally. It also exhibits antipyretic activity. Codeine is a centrally acting analgesic which produces its effect by its action at opioid-binding sites (μ-receptors) within the CNS. It is a full agonist. Co-codamol 30/500mg effervescent tablets are indicated for the relief of severe pain.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 24837/0004
PROPRIETARY NAME:	Co-codamol 30/500mg effervescent tablets
ACTIVE INGREDIENT/S:	paracetamol, codeine phosphate hemihydrate
COMPANY NAME:	Consilient Health Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	POM

1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Co-codamol 30/500mg effervescent tablets. The proposed MA holder is 'Consilient Health Limited, 5th floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland'.

The reference product is Co-codamol effervescent tablets 30/500mg (PL 25099/0028), held by Zanza Laboratories Limited. The test and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the product is Co-codamol 30/500mg effervescent tablets. The product has been named in line with current requirements.

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

Co-codamol 30/500mg effervescent tablets contain the active ingredients paracetamol and codeine phosphate hemihydrate. Each effervescent tablet contains 30 mg of codeine phosphate hemihydrate (codeine base 22.5 mg) and 500 mg of paracetamol. The tablets are marketed in polypropylene tubes with polyethylene stoppers, with silica gel as desiccant, each tube containing 15 or 20 tablets. The tubes are placed with the Patient Information Leaflet (PIL) into cardboard outer cartons and presented in packs of 30 (2 tubes of 15) and 100 (5 tubes of 20) effervescent tablets.

The approved shelf-life (2 years) and storage conditions (Do not store above 25°C, Keep the container tightly closed) are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is a POM licensed medicine available on prescription.

2.4 Marketing authorisation holder / Contact Persons / Company

The proposed Marketing Authorisation holder is 'Consilient Health Limited, 5th floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland'.

The QP responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers

The proposed manufacturing site is consistent with that 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 in line 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

No materials of animal or human origin are included in the products.

3. EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of experts were provided, as appropriate.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is consistent with 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) / CARTON

The patient information leaflet has been prepared in line with the details registered for the cross-reference product. The approved PIL is satisfactory.

Colour 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.

7. CONCLUSIONS

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

PRECLINICAL ASSESSMENT

The application was submitted as a simple, abridged application, according to Article 10c of Directive 2001/83/EC, as amended.

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical overview has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

As this is a duplicate application for PL 25099/0028, no new clinical data have been supplied with the application and none are required. A clinical overview has been written by a suitably qualified person and is satisfactory.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with that previously assessed for the cross-reference 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 the previously granted MA for Co-codamol effervescent tablets 30/500mg (PL 25099/0028), held by Zanza Laboratories Limited

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC, PIL and labelling are satisfactory and consistent with those for the cross-reference product.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

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 and sufficient space has been included for a standard UK pharmacy dispensing label. The Marketing Authorisation Holder (MAH) has stated that not all pack sizes may be marketed. However, they have committed to submitting mock-ups for all packaging for assessment before they are commercially marketed.

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-reference product. Extensive clinical experience with paracetamol and codeine combination products is considered to have demonstrated the therapeutic value of the product. The risk: benefit is, therefore, considered to be positive.

CO-CODAMOL 30 / 500 MG EFFERVESCENT TABLETS

(codeine phosphate hemihydrate, paracetamol)

PL 24837/0004

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the marketing authorisation application on 7th February 2008

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 18th February 2008

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 20th May 2008

4 The applicant responded to the MHRA's request, providing further information for the quality sections on 6th August 2008

5 The application was determined on 3rd November 2008

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Co-Codamol 30/500 mg Effervescent Tablets is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Co-Codamol 30/500 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:
30 mg of codeine phosphate hemihydrate (codeine base 22.5 mg) and 500 mg of paracetamol.
Excipients:

Each tablet contains 410 mg sodium. Also contains sorbitol. See section 4.4 for further information.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet
White, bevelled, flat, round tablets with a break-line on one side.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the relief of severe pain.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Co-Codamol 30/500 mg Effervescent Tablets are for oral use and should be dissolved in at least half a tumbler-full of water before taking.
Adults: One or two effervescent tablets not more frequently than every 4 hours, up to a maximum of 8 tablets in any 24 hour period.
Elderly: As for adults, however a reduced dose may be required. See warnings.
Children: Not recommended for children under 12 years of age.

4.3 CONTRAINDICATIONS

Hypersensitivity to paracetamol or codeine which is rare, or hypersensitivity to any of the other constituents. Conditions where morphine and opioids are contraindicated eg, acute asthma, respiratory depression, acute alcoholism, head injuries, raised intra-cranial pressure and following biliary tract surgery; monoamine oxidase inhibitor therapy, concurrent or within 14 days.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Each effervescent tablet contains 410mg sodium (17.83mEquivalents). This sodium content should be taken into account when prescribing for patients in whom sodium restriction is indicated.

Care should be observed in administering the product to any patient whose condition may be exacerbated by opioids, particularly the elderly, who may be sensitive to their central and gastro-intestinal effects, those on concurrent CNS depressant drugs, those with prostatic hypertrophy and those with inflammatory or obstructive bowel disorders. Care should also be observed if prolonged therapy is contemplated.

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 alcoholic liver disease.

Patients should be advised not to exceed the recommended dose and not take other paracetamol containing products concurrently.

Co-codamol 30/500 mg Effervescent Tablets contain sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Paracetamol may increase the elimination half-life of chloramphenicol. Oral contraceptives may increase its rate of clearance. 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.

The effects of CNS depressants (including alcohol) may be potentiated by codeine.

4.6 PREGNANCY AND LACTATION

There is inadequate evidence of the safety of codeine in human pregnancy, but there is epidemiological evidence for the safety of paracetamol. Both substances have been used for many years without apparent ill consequences and animal studies have not shown any hazard. Nonetheless careful consideration should be given before prescribing the products for pregnant patients. Opioid analgesics may depress neonatal respiration and cause withdrawal effects in neonates of dependent mothers.

Paracetamol is excreted in breast milk but not in a clinically significant amount.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients should be advised not to drive or operate machinery if affected by dizziness or sedation.

4.8 UNDESIRABLE EFFECTS

Codeine can produce typical opioid effects including constipation, nausea, vomiting, dizziness, light-headedness, confusion, drowsiness and urinary retention. The frequency and severity are determined by dosage, duration of treatment and individual sensitivity. Tolerance and dependence can occur, especially with prolonged high dosage of codeine.

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.

4.9 OVERDOSE

Nausea and vomiting are prominent symptoms of codeine toxicity and if there is evidence of circulatory and respiratory depression, suggested treatment is gastric lavage and catharsis. If CNS depression is severe, assisted ventilation, oxygen and parenteral naloxone may be needed.

Patients in whom oxidative liver enzymes have been induced, including alcoholics and those receiving barbiturates and patients who are chronically malnourished, may be particularly sensitive to the toxic effects of paracetamol in 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, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Liver damage is likely in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

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 and any patient who had ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Natural opium alkaloids

ATC code: N02A A59.

Paracetamol is an analgesic which acts peripherally, probably by blocking impulse generation at the bradykinin sensitive chemo-receptors which evoke pain. Although it is a prostaglandin synthetase inhibitor, the synthetase system in the CNS rather than the periphery appears to be more sensitive to it. This may explain paracetamol's lack of appreciable anti-inflammatory activity. Paracetamol also exhibits antipyretic activity.

Codeine is a centrally acting analgesic which produces its effect by its action at opioid-binding sites (m-receptors) within the CNS. It is a full agonist.

5.2 PHARMACOKINETIC PROPERTIES

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentration occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

Codeine and its salts are absorbed from the gastro intestinal tract. Ingestion of codeine phosphate hemihydrate produces peak plasma codeine concentrations in about one hour. Codeine is metabolised by O- & N-demethylation in the liver to morphine and norcodeine. Codeine and its metabolites are excreted almost entirely by the kidney, mainly as conjugates with glucuronic acid.

The plasma half-life has been reported to be between 3 and 4 hours after administration by mouth or intravascular injection.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium hydrogen carbonate

anhydrous sodium carbonate

anhydrous citric acid

sodium docusate

sorbitol (E420)

saccharin sodium

dimeticone

sodium benzoate

macrogol 6000

natural grapefruit flavour consisting of maltrodextrine, gum arabic, sorbitol, grapefruit oil and grapefruit top note

6.2 INCOMPATIBILITIES

Not applicable

6.3 SHELF LIFE

2 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C. Keep the container tightly closed.

6.5 NATURE AND CONTENTS OF CONTAINER

Polypropylene tubes with polyethylene stoppers with silica gel as desiccant, each containing 15 or 20 tablets.

The tubes are presented in packs of 30 (2 tubes of 15) and 100 (5 tubes of 20) effervescent tablets.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Consilient Health Limited,
5th floor, Beaux Lane House,
Mercer Street Lower,
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 24837/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/10/2008

10 DATE OF REVISION OF THE TEXT

31/10/2008

PRODUCT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

CONSILIENT HEALTH Ltd.

Co-codamol 30/500 mg Effervescent Tablets

(codeine phosphate and paracetamol)

Important information about Co-codamol

- Taking codeine regularly for a long time can lead to addiction. This means that when you stop taking the tablets, you might feel restless and irritable
- Do not take this medicine for longer than your doctor tells you
- Taking a painkiller for headaches too often, or for too long, can make them worse

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this Leaflet:

1. WHAT CO-CODAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Co-codamol 30/500 mg Effervescent Tablets (called Co-codamol in this leaflet).
Co-codamol contains two different medicines called:

- Codeine
- Paracetamol

These medicines both belong to a group of medicines called pain-killers (analgesics)
Co-codamol is used to provide relief from severe pain.

2. BEFORE YOU TAKE CO-CODAMOL

Do not take Co-codamol if:

- You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients (listed in Section 6 below)
- You have severe asthma attacks or severe breathing problems
- You have recently had a head injury
- You have recently had an operation on your gall bladder or a similar operation
- You have raised pressure in your brain
- You are taking a medicine for depression called an MAOI (monoamine oxidase inhibitor). This also applies if you have taken them in the last 14 days
- You are an alcoholic

Do not take Co-codamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-codamol.

Take special care with Co-codamol

Check with your doctor or pharmacist before taking Co-codamol if:

- You are pregnant or breast-feeding (see Pregnancy and breast-feeding section below)
- You have severe kidney or liver problems
- You have problems with your prostate (such as difficulty passing water)
- You have a bowel problem
- You are elderly

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-codamol.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Co-codamol can affect the way some other medicines work. Also some other medicines can affect the way Co-codamol works.

While taking Co-codamol you should not take any other medicines which contain paracetamol or codeine

This includes other pain-killers, and some cough and cold remedies. It also includes other medicines available from your pharmacist and more widely in shops. Always check the name of the medicines inside anything you buy or are prescribed, to see if they contain paracetamol or codeine.

Do not take this medicine and tell your doctor if you are taking:

- Medicines for depression called MAOIs (monoamine oxidase inhibitors). Also do not take if you have taken them in the last 14 days

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines which make you sleepy including alcohol
- Medicines used to thin the blood (such as warfarin)
- Chloramphenicol - an antibiotic
- Metoclopramide or domperidone - used for feeling sick (nausea) or being sick (vomiting)
- Cholestyramine - used for high cholesterol and fat levels in the blood
- Oral contraceptives such as 'the pill'

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Co-codamol.

Taking Co-codamol with food and drink

Drinking alcohol while taking this medicine can make you feel sleepy.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

Driving and using machines

You may feel sleepy or dizzy after taking Co-codamol. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of this medicine

- **Sodium:** There is about 410 mg of sodium in each Co-codamol Tablet. This may be harmful to people on a low sodium diet
- **Sorbitol:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to sugars), talk to your doctor before taking this medicine

3. HOW TO TAKE CO-CODAMOL

Always take Co-codamol as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Do not take more than the dose you have been told**
- **Do not take for longer than your doctor tells you**

How much to take

Adults and children over 12 years of age

- Dissolve the tablets in half a glass of water
- The usual dose of Co-codamol is 1 or 2 tablets
- Leave at least 4 hours between each dose of Co-codamol
- Do not take more than 8 tablets in any 24 hour period
- Elderly people may be given a lower dose

Children

- Co-codamol is not recommended for use in children under 12 years of age.

If you think that the effect of Co-codamol is too strong or too weak, talk to your doctor or pharmacist.

Changing the dose after taking Co-codamol regularly for a long time

Taking Co-codamol regularly and for a long time can make you addicted to the medicine. If you have taken regular daily doses of Co-codamol for a long time, talk to your doctor before increasing the dose or before suddenly stopping treatment.

If you take more Co-codamol than you should

- If you take more Co-codamol than you should, talk to your doctor or go to a hospital straight away. This is because there is a risk of serious liver damage, though this may not happen straight away
- Remember to take this medicine pack and any remaining tablets with you, so the doctor knows what you have taken

If you forget to take Co-codamol

- If you forget a dose, do not worry, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose
- Do not take a double dose to make up for a forgotten dose
- Remember to leave at least 4 hours between doses

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol can cause side effects, although not everybody gets them.

Important side effects you should know about Co-codamol

- Taking codeine regularly for a long time can make you addicted to the medicine. This means that when you stop taking the tablets, you might feel restless and irritable
- Taking a painkiller for headaches too often or for too long can make them worse

Stop taking Co-codamol and see a doctor straight away if:
- You develop an allergic reaction. Signs of an allergic reaction include a rash, swelling of your face, lips, mouth and throat, difficulty swallowing or difficulty breathing

Talk to your doctor as soon as possible if:
- You have problems passing urine
- You notice that you bruise or bleed more easily than usual. Also, if you get more infections than usual, such as a sore throat or mouth ulcers

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:
- Constipation
- Feeling sick (nausea) or being sick (vomitting)
- Feeling dizzy, light-headed or sleepy
- Feeling confused

If any of the side effects get serious or lasts for longer than a few days or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CO-CODAMOL

Keep out of the reach and sight of children.

Do not use Co-codamol after the expiry date stated on label. The expiry date refers to the last day of the month.

Store your medicine in the original container and keep the container tightly closed in order to protect from moisture.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Co-codamol 30/500 mg Effervescent Tablets contain:
- The active ingredients are codeine phosphate and paracetamol. Each tablet contains 30 mg of codeine phosphate and 500 mg of paracetamol
- The other ingredients are sodium hydrogen carbonate, anhydrous sodium carbonate, anhydrous citric acid, sodium docusate, sorbitol, saccharin sodium, dimeticone, sodium benzoate, macrogol 6000 and natural grapefruit flavour

What Co-codamol 30/500 mg Effervescent Tablets look like and the contents of the pack:
Co-codamol 30/500 mg Effervescent Tablets are white, bevelled, flat, round tablets with a break-line on one side. They are available as packs of 30 or 100 effervescent tablets, in tubes within an outer carton.

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder:
Consilient Health Ltd.
5th floor, Beaux Lane House,
Mercer Street Lower, Dublin 2,
Ireland

Manufacturer:
Creapharm Gannat SAS
Z.I. Le Malcourlet, 03800 Gannat
France

Date of leaflet revision: June 2008

LABELLING

Carton – 100 tablet pack size

Translation of Braille on carton

Tube label