Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paracodol Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
Paracetamol	500 mg
Codeine phosphate	8 mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablets.
White, effervescent tablets with bevelled edges and flat faces.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic in the relief of mild to moderate pain as associated with rheumatism, neuralgia, musculoskeletal disorders, headache, migraine, toothache, sore throat, period pains, discomfort associated with influenza, feverishness and feverish colds.

4.2 Posology and method of adminstration

For oral administration.

Recommended dosage
Adults:
The usual dose is 1 - 2 tablets, which may be repeated every four to six hours or as directed by the physician. The maximum 24 hour dose is 8 tablets.

Children:
Children 6 - 12 years: ½ - 1 tablet with a maximum of 4 tablets in any 24 hour period.

If symptoms persist for more than 3 days a doctor should be consulted.

Children under 6 years: Not recommended.

4.3 Contraindications

Hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

The tablet base contains 420 mg of sodium. This should be kept in mind if long term treatment is contemplated in patients on a low salt diet.

Paracetamol should only be used with caution in patients with liver dysfunction.

Prolonged use except under medical supervision can be harmful. If symptoms persist, the physician should be consulted.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol should be given with care to patients taking other drugs which affect the liver.

4.6 Pregnancy and lactation

There is epidemiological evidence of safety of paracetamol and inadequate evidence of safety of codeine in pregnancy. Codeine has been used for many years without apparent ill-consequences, and animal studies have not shown any hazard. The use of Paracodol Tablets in pregnancy is therefore acceptable if there is no safer alternative. Use during lactation is acceptable.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects with paracetamol are rare in therapeutic doses. Paracetamol has been widely used and reports of adverse reactions are rare and generally associated with overdosage. Codeine may sometimes cause constipation.

4.9 Overdose

It is unlikely that a toxic dose of a large effervescent tablet would be ingested. In the event of an overdose, the toxic effect of codeine may be reversed by the administration of naloxone injection. Symptoms of paracetamol overdose are often delayed for at least 24 hours but to prevent hepatic damage, treatment should be given as soon as possible and within 10 hours of ingestion.

Treatment is by the administration of oral methionine, oral or intravenous acetylcysteine.

In cases of paracetamol overdosage, liver microsomal inducing agents such as barbiturates, tricyclic antidepressants, and alcohol may increase the hepatotoxicity of paracetamol. Avoid alcohol.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracodol is a combination of the analgesic, antipyretic paracetamol and the narcotic analgesic, codeine phosphate.

5.2 Pharmacokinetic properties

Paracetamol is well absorbed, has a Tmax of ½ - 2 hours, is metabolised extensively in the liver, with a T½ of 1-4 hours. Elimination is mainly via the kidney.

Codeine phosphate is well absorbed, has a Tmax of 1 hour, is metabolised to morphine and other metabolites in the liver, with a T½ of 3-4 hours and is excreted mainly via the kidney.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate
Anhydrous citric acid
Anhydrous sodium carbonate
Dried sodium benzoate
Saccharin sodium
Docusate sodium

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

6.5 Nature and contents of container

Aluminium foil/polyethylene laminate strips in cartons. Pack sizes 2, 10, 12, 24, 30 and 100.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
Bayer House
Strawberry Hill
Newbury
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RG14 1JA
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8 MARKETING AUTHORISATION NUMBER

PA 21/71/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 23 January 2003

10 DATE OF REVISION OF THE TEXT

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