

Product Summary

1. Trade Name of the Medicinal Product

Co-dydramol Tablets

2. Qualitative and Quantitative Composition

Dihydrocodeine Tartrate BP	10.0	mg
Paracetamol BP	500.0	mg

3. Pharmaceutical Form

Tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- a) As an analgesic.
- b) As an antitussive.

4.2. Posology and method of administration

Codydramol tablets should be taken, if possible, during or after meals.

As an analgesic:

Adults and children over 12 years: 1 tablet every four hours. This may if necessary be increased to 2 tablets four times daily.

As an antitussive:

Adults and children over 12 years: 1 tablet every four hours.

Not recommended for children under 12 years.

Dosage should be reduced in the elderly.

Do not exceed 8 tablets in 24 hours.

For oral administration.

4.3. Contraindications

Respiratory depression, obstructive airway disease, allergic disorders, during an attack of asthma.

4.4 Special warnings and precautions for use

Use with precaution in impaired liver function or renal disease. Reduce dosage in hypothyroidism and in chronic hepatic disease. May cause constipation, nausea, vertigo & giddiness in some patients.

The risk-benefit of continued use should be assessed regularly by the prescriber.

The leaflet will state in a prominent position in the 'before taking' section

- Do not take for longer than directed by your prescriber
- Taking codeine/dihydrocodeine (DHC) regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

The label will state (To be displayed prominently on outer pack- not boxed):

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

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

Additive CNS depression may occur with alcohol.

4.6. Pregnancy and lactation

There is no evidence of safety in human pregnancy or of secretion in human milk.

4.7. Effects on ability to drive and use machines

None stated.

4.8. Undesirable effects

Regular prolonged use of codeine/DHC is known to lead to addiction and symptoms of restlessness and irritability may result when treatment is then stopped.

Prolonged use of a pain killer for headaches can make them worse.

4.9. Overdose

Codeine

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

Symptoms

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

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 350 mg or a child more than 5 mg/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.

Paracetamol

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

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

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 NPIS or a liver unit.

Pharmacological Properties

5.1. Pharmacodynamic Properties

Dihydrocodeine tartrate is a potent analgesic with well defined anti-tussive properties. Paracetamol has analgesic and anti-pyretic actions similar to those of aspirin but has no useful anti-inflammatory properties.

5.2. Pharmacokinetic Properties

The pharmacokinetics of dihydrocodeine may be similar to those of codeine; they differ between subjects with normal renal function and those with chronic renal failure treated with haemodialysis.

Dihydrocodeine is well absorbed from the gastrointestinal tract following oral administration, and a small quantity is bound to plasma proteins. Peak levels of plasma dihydrocodeine concentration are attained in an hour following ingestion. Plasma half-life has been reported to be 3-4 hours after oral ingestion. Dihydrocodeine is metabolised in the liver by O- and N-demethylation. Dihydrocodeine and its metabolites are excreted entirely by the kidneys mainly as conjugates with glucuronic acid.

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentration occurring 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and the sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from 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 small amounts by mixed-function oxidases in liver and which is usually de-toxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and may cause liver damage.

5.3. Preclinical Safety Data

Not applicable

Pharmaceutical Particulars

6.1. List of Excipients

Starch, povidone (K=29/32), sodium starch glycollate, stearic acid, colloidal silicone dioxide, talc.

6.2. Incompatibilities

None stated

6.3. Shelf Life

1 year

6.4. Special Precautions for Storage

Store in a cool dry place protected from light below 25°C.

6.5. Nature and Contents of Container

Securitainers containing 25, 50, 100, 250, 500 or 1000 tablets.

6.6. Instruction for Use/Handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Forley Generics Ltd
NLA Tower
12-16 Addiscombe Road
Croydon
CR0 0XT
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 16201/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/03/2009

10 DATE OF REVISION OF THE TEXT

06/03/2009