Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solpadeine Soluble Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 500mg paracetamol, 8mg codeine phosphate hemihydrate and 30mg caffeine.

Excipients:

Sorbitol (E420)

Sodium

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet.

Product imported from the UK:
Flat, white tablets with bevelled edges, plain on one side and a breakline on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of symptoms of headache, including migraine, toothache, backache, common cold, influenza, menstrual pain, musculoskeletal pain.

4.2 Posology and method of administration

Adults (including the elderly)
Two tablets dissolved in a glass of water three to four times in a 24 hour period as required. The dose should not be repeated more frequently than every four hours.

Children

7-12 years: Half to one tablet dissolved in water, which may be repeated three to four times in a 24 hour period as required. Children should not be given doses of Solpadeine more frequently than every four hours and not more than four doses should be given in any 24 hour period.

The product is not suitable for children under 7 years of age except on medical advice.

For oral administration only.

4.3 Contraindications

Hypersensitivity to paracetamol, codeine, caffeine or any of the other constituents.

Acute asthma.

Use of codeine containing products is contraindicated in mothers who are breastfeeding unless prescribed by a doctor.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater than in those with non-cirrhotic alcoholic liver disease.

Care should be observed in administering the product to any patients whose condition may be exacerbated by opioids, particularly the elderly, who are especially sensitive to their central and gastro-intestinal effects, those on concurrent CNS depressant drugs, those with prostate hypertrophy and those with inflammatory or obstructive bowel disorders.

Excessive intake of tea and coffee should be avoided while taking Solpadeine. 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.

Prolonged use without medical supervision may be harmful.

Do not exceed the stated dose.

If symptoms persist, consult your doctor.

Keep out of reach of children.

CONTAINS PARACETAMOL. Do not take with other paracetamol containing medicines.

The product should be used with caution in patients with hypertension, oedema or renal insufficiency becuase of the sodium content.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced cholestramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Opioid analgesics should be given with care to patients receiving monamine oxidase inhibitors. The effect of CNS depressants (including alcohol) may be potentiated by codeine; these interactions are unlikely to be significant at the dosage involved.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence for the safety of codeine in human pregnancy, but epidemiological studies in human pregnancy have shown no ill effects due to paracetamol and caffeine used in the recommended dosage. Patients should follow the advice of their doctor regarding its use.

Paracetamol and caffeine are excreted in breast milk but not in a clinically significant amount. Insignificant levels of codeine also pass into breast milk. Available published data do not contraindicate breast feeding.

In nursing mothers, who are ultra-rapid metabolisers of codeine, higher than expected serum and breast milk morphine levels can occur. Morphine toxicity in babies can cause excessive somnolence, hypotonia, miosis and difficulty breastfeeding or breathing. In severe cases respiratory depression and death can occur. In severe cases, naloxone may be appropriate to reverse the effects. The lowest effective dose should be used, for the shortest possible time.

Nursing mothers should be informed about carefully monitoring the infant during treatment for any signs and/or symptoms of morphine toxicity such as increased drowsiness or sedation, difficulty breastfeeding, breathing difficulties, miosis and decreased tone, and seeking immediate medical care if such symptoms or signs are noticed. The

nursing mother should be informed about monitoring for signs and symptoms of maternal opioid toxicity as well. Should such signs/symptoms be noted in mother or baby, the mother should immediately stop taking all codeine-containing medicines and seek medical advice.

Codeine-containing products must not be used while breastfeeding unless prescribed by a doctor.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. Codeine may cause consitpation, nausea, dizziness and drowsiness according to dosage and individual susceptibility.

4.9 Overdose

Immediate medical attention (in-hospital, if possible) is required in the event of overdose, even if there are no significant early symptoms. There may be no early symptoms following a life-threatening overdose. Ingestion of more that 12 g paracetamol (24 standard 500 mg tablets) or more than 150 mg paracetamol per kg bodyweight (9 g paracetamol in a 60 kg individual), whichever is the smaller, can cause severe liver damage. Liver damage (as demonstrated by a rise in plasma transaminase levels) may be apparent between 8 and 36 hours following overdose. Biochemical evidence of maximal damage, however, may not be attained until 72-96 hours after ingestion of the overdose.

Intravenous N-acetylcyteine (NAC) is effective when initiated within 8 hours of the overdose. Efficacy declines progressively after this time, but NAC may provide some benefit up to and possibly beyond 24 hours. Oral methionine is also effective provided that it is given within 10 to 12 hours of the overdose. There is little evidence that undertaking gastric lavage will be on benefit to a patient in whom paracetamol is known to have been the only substance ingested. Symptoms of paracetamol overdose in the first 24 hours may include pallor, nausea, vomiting, anorexia, and abdominal pain. Abnormailites of glucose metabolism and metabolic acidosis may occur. In severe poisoning , hepatic failure may progress to encephalopathy, coma and death. Liver damage results when the excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

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.

Overdose of caffeine may produce nervousness, restlessness, insomnia, excitement, diuresis, facial flushing, muscle twitching, GI disturbance, tachycardia or cardiac arrythmia, "rambling" flow of thought and speech, psychomotor agitation, or periods of inexhaustability.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is an analgesic and antipyretic. Codeine phosphate is a moderate analgesic and has weak cough suppressant activity. Caffeine is a potent stimulator of the CNS.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. It is relatively uniformly distributed throughout most bodily fluids and exhibits variable protein binding. Excretion is almost completely renal, in

the form of conjugated metabolites.

Caffeine is absorbed readily after oral administration, maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours. 65-80% of administered caffeine is excreted in the urine as I-methyluric acid I-methylxanthine.

Codeine phosphate is well absorbed after oral administration and is widely distributed. About 86% is excreted in the urine in 24 hours; 40-70% is free or conjugated norcodeine, 5-15% is free or conjugated morphine and 10-20% is free or conjugated norcodeine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate

Sorbitol powder (E420)

Saccharin sodium

Sodium laurilsulfate

Citric acid

Sodium carbonate

Povidone

Silicone fluid

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Solpadeine soluble tablets are packed into PPFP or Surlyn laminate strips and then into cardboard cartons. Pack size 12 tablets.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 465/181/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 22nd September 2006

10 DATE OF REVISION OF THE TEXT

April 2011