Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Syndol Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol 450mg
Codeine Phosphate Hemihydrate 10mg
Doxylamine succinate 5mg
Caffeine 30mg

Excipients: contains lactose monohydrate and Sunset Yellow Aluminium Lake (E110).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:
Yellow, capsule shaped tablet, embossed 'Syndol' on one side with a single breakline on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief in tension headache and other pains of a similar tension state origin. For the symptomatic relief of pain following surgical and dental operations and procedures.

4.2 Posology and method of administration

Adults and children over 12 years
Take 1 or 2 tablets every four to six hours as need for relief. Do not exceed 8 tablets per day. Not recommended for children under 12 years.

4.3 Contraindications

Use in patients hypersensitive to any of the ingredients.

4.4 Special warnings and precautions for use

The product should not be administered to children under the age of 12 years unless prescribed specifically by the physician.

The use of this product may induce drowsiness. Persons should not drive or operate machinery unless this effect has been shown not to occur.

It is dangerous to exceed the recommended dose. 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.

This product should only be used when clearly necessary. If symptoms persist or become worse, consult your doctor. Do not take any other paracetamol containing products.
Immediate medical advice should be sought in the event of overdosage.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sunset Yellow Aluminium Lake (E110) - May cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Alcoholic drink should be avoided.

4.6 Fertility, pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Caution is advised as this medicine may lead to drowsiness and impaired concentration aggravated by simultaneous intake of alcohol or other central nervous system depressant agents.

4.8 Undesirable effects

Doxylamine Succinate may cause drowsiness or dizziness. Codeine component may result in mild constipation. Agranulocytosis is a very rare complication with paracetamol treatment.

4.9 Overdose

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

Immediate treatment is essential in the management of a paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol in the proceeding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetycysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available. While the dose of Codeine Phosphate hemihydrate in this preparation is relatively small and therefore less likely to prove a problem, symptoms of overdosage include cold clammy skin, confusion, convulsions, dizziness, drowsiness, nervousness or relentlessness, miosis, bradycardia, dyspnoea, unconsciousness and weakness. Codeine in large doses may produce respiratory depression, hypotension, circulatory failure and deepening coma. Death may occur from respiratory failure.

Initial treatment includes emptying the stomach by aspiration and lavage. Intensive support therapy may be required to correct respiratory failure and shock. In addition the specific narcotic antagonist, naloxone hydrochloride, may be used rapidly to counteract the severe respiratory depression and coma.

A dose of 0.4-2 mg is given intravenously or intramuscularly to adults, this is repeated at intervals of 2-3 minutes; if necessary up to 10mg of naloxone may be given. In children doses of 5-10µg/kg body weight may be given intravenously or intramuscularly. Codeine is not dialysable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic properties. Codeine Phosphate hemihydrate is an analgesic. Doxylamine Succinate is an antihistamine and Caffeine is a mild stimulant.

5.2 Pharmacokinetic properties

The pharmacokinetics of paracetamol, codeine phosphate hemihydrate and caffeine are widely published. Doxylamine succinate is readily absorbed from the gastrointestinal tract. Following oral administration the effects start with 15 to 30 minutes and peak within 1 hour. In humans 60-80% of doxylamine has been recovered in urine at 24 hours post-dose.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch
Povidone
Talc
Magnesium stearate
Croscarmellose sodium
Hypromellose
Polyethylene glycol 400
Quinoline Yellow Aluminium Lake (E104)
Sunset Yellow Aluminium Lake (E110)
Titanium Dioxide
Lactose monohydrate
Polyethylene glycol 4000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister label 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

Blister packs containing 10 and 20 tablets in an over-labelled outer carton.

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

G & A Licensing Ltd
Ballymurray
Co. Roscommon

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1447/66/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th of June 2010.

10 DATE OF REVISION OF THE TEXT