Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol, Codeine, Caffeine and Doxylamine Film-coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol	450.00	mg
Codeine Phosphate	10.00	mg
Doxylamine Succinate	5.00	mg
Caffeine	30.00	mg

3 PHARMACEUTICAL FORM

Film-coated Tablet

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 or 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.

Do not exceed the stated 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 an overdose, even if you feel well.

4.5 Interaction with other medicinal products and other forms of interaction

Alcoholic drink should be avoided.

4.6 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

Immediate medical advice should be sought in the event of an overdose, even if you feel well. Treat symptomatically as for paracetamol and codeine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

The pharmacokinetics of paracetamol, codeine phosphate 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
Croscarmellose sodium
Povidone
Talc
Magnesium stearate
Opadry II yellow (lactose monohydrate, titanium dioxide, quinoline yellow (E104), FD & C yellow/sunset yellow (E110), macrogol 4000).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister Strips: 250 micron UPVC/PVDC and aluminium foil 20 micron coated with lacquer containing 50, 24, 20, 10 or 4* tablets. The blister strips are presented in cardboard cartons.
* Sample pack.

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

SSL International Plc
Venus
1 Old Park Lane
Trafford Park
Manchester M41 7HA
UK

8 MARKETING AUTHORISATION NUMBER

PA 1138/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 September 2009

10 DATE OF REVISION OF THE TEXT

September 2009