Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ilvico Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:		
Paracetamol	250	mg
Calcium Ascorbate	36	mg (equivalent to ascorbic acid 30mg)
Caffeine Monohydrate	10	mg
Brompheniramine Maleate	3	mg
Also Contains		
Sucrose	206.5	mg
Lactose	63.7	mg
Wheat flour	19.0	mg

For a full list excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated tablet. (Tablet)

Off-white, shiny, round, highly biconvex sugar-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of symptoms associated with the common cold, influenza and upper respiratory tract infections.

4.2 Posology and method of administration

Adults and children over 12 years:

One or two tablets taken orally with water three times daily.

Children 6-12 years and the elderly:

One tablet two or four times daily taken orally with water.

4.3 Contraindications

1. Ilvico must not be used in the presence of narrow-angle glaucoma.
2. Hereditary glucose-6-phosphate dehydrogenase deficiency (risk of haemolytic anaemia).
3. Hypersensitivity to Paracetamol or any of the other ingredients.
4. For pregnancy and nursing mothers.
5. Use in children less than 6 years old.
6. Use in patients with tachyarrhythmias.

4.4 Special warnings and precautions for use

1. This product contains paracetamol and should be administered with care to patients with impaired liver or renal function.

2. As this product contains an antihistamine, it may act as a cerebral stimulant in children and occasionally in adults giving rise to insomnia, nervousness, hyperpyrexia, tremors and epileptiform convulsions.

4.5 Interaction with other medicinal products and other forms of interaction

In simultaneous use with drugs which cause enzyme induction in liver, e.g. certain hypnotics and antiepileptics, liver damage may be caused with paracetamol doses which are otherwise not harmful. The same applies to alcohol abuse. When gastric emptying is slowed, e.g. due to propantheline, the rate of paracetamol absorption may be reduced resulting in later onset action. When gastric emptying is accelerated, e.g. after administration of metoclopramide, the rate of absorption is increased. The half life of chloramphenicol may be prolonged in combinations of chloramphenicol with the risk of increased toxicity. Paracetamol may potentiate the anticoagulant effect of warfarin and coumarin derivatives slightly. The clinical relevance, however, cannot yet be assessed. Patients undergoing treatment with oral anticoagulants should therefore only receive paracetamol over prolonged periods under medical supervision.

Simultaneous administration of paracetamol and AZT enhances the tendency to develop neutropenia. Therefore, the agent is to be administered simultaneously with AZT only if recommended by a physician.

Salycamide prolongs the elimination half-life of paracetamol and thus effects an increased accumulation of its hepatotoxic metabolite.

Ilvico may potentiate the effect of agents with central depressant action, e.g. analgesics and tranquillizers, alcohol and vice versa, if MAOIs and tricyclic antidepressants are administered simultaneously, the adrenergic or anticholinergic effects may be potentiated.

4.6 Fertility, pregnancy and lactation

Paracetamol passes the placental barrier and is found in breast milk according to the mother's plasma concentrations. A mean concentration of 11 µg/ml was measured in the milk after a single dose of 650mg. Ilvico should only fundamentally be given if there are compelling reasons.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness, therefore, if affected patients should refrain from driving or operating machinery.

4.8 Undesirable effects

Hypersensitivity reactions may occur after administration of drugs containing paracetamol (very rarely, skin reactions; thrombocytopenia or leukopenia have been described). Agranulocytosis or pancytopenia have been observed in individual cases: bronchospasms have been triggered in predisposed persons (analgesic asthma). Isolated cases of Quincke's oedema, dyspnoea, sweating, nausea and a drop in blood pressure to the point of shock have also been described for the active constituent paracetamol. The antihistamine component may produce sedation, dry mouth and in rare cases excitation.

Side effects include drowsiness, dizziness, ataxia, paraesthesia, headache and restlessness. Hypertension has also been reported rarely.

4.9 Overdose

If paracetamol intoxication is suspected, gastric lavage is indicated in the first 6 hours after overdosage. The

paracetamol plasma concentration can be lowered by dialysis. Binding of the cytotoxic metabolite can be achieved by intravenous administration of SH group donors, such as cysteamine or N-acetylcysteine, if possible within 8 hours after intoxication.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Magnesium stearate
Corn starch
Silicon dioxide
Carmellose sodium
Cellulose powder
Lactose
Carnauba wax
Bleached wax
Methylcellulose
Glycerol
Povidone
Gelatin
Calcium carbonate
Acacia
Wheat flour
Kaolin
Talc
Titanium oxide
Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years (from date of manufacture)

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister pack consisting of PVC coated with PVDC, heat sealed onto aluminium foil.
Pack size: 20 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 MARKETING AUTHORISATION HOLDER

Seven Seas Limited
Hedon Road
Marfleet
Hull HU9 5NJ

8 MARKETING AUTHORISATION NUMBER

PA 417/10/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 1984
Date of last renewal: 12th June 2009

10 DATE OF REVISION OF THE TEXT

December 2010