Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicobrevin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 15 mg of anhydrous quinine, 100 mg of menthyl valerate, 10 mg of camphor and 10 mg of eucalyptus oil.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Capsule, soft

Clear, translucent, oval-shaped, soft gelatin capsule, filled with a clear, amber-coloured liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Stop smoking support course designed to provide therapeutic support to those trying to give up smoking.

4.2 Posology and method of administration

Adults only. Each capsule should be swallowed whole with a little water. The course is started in the evening, taking two capsules the first evening before retiring. For the next six days take one capsule on an empty stomach each morning and two capsules each evening before retiring. For the next seven days take one capsule on an empty stomach each morning and one capsule each evening before retiring. For the next fourteen days take one capsule each evening before retiring. This completes the four week course.

4.3 Contraindications

Use in children. Hypersensitivity to the active ingredients.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Not recommended during pregnancy or during lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

There is no evidence from clinical studies, which show that the use of NICOBREVIN is associated with an increased incidence of severity of adverse events compared to placebo.

4.9 Overdose

In the case of deliberate overdosage with more than one complete pack, the most serious consequences would result from the quinine content. As there is no specific antidote to this or any other of the ingredients in NICOBREVIN, support management of overdosage should be undertaken. Gastric lavage may be performed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

NICOBREVIN contains (a) quinine, which has some effect on alleviating the effects of smoking withdrawal on tobacco craving, metabolism and appetite in addition to (b) the carminatives camphor, menthol and eucalyptus oil. Menthyl valerate helps relieve the irritability experienced by persons who give up smoking.

5.2 Pharmacokinetic properties

The product contains well tried active substances known for a long time.

The information available from the literature indicates that the elimination of the active ingredients is achieved without significant build up in chronic toxicity. NICOBREVIN is intended for a 28-day course of treatment and not for chronic therapy. Toxicity to prolonged treatment is unlikely.

5.3 Preclinical safety data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oleic acid
Arachis oil (peanut oil)
Glycerol
Gelatin
Sodium propyl hydroxybenzoate
Sodium ethyl hydroxybenzoate

6.2 Incompatibilities

None.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

No special precautions.

6.5 Nature and contents of container

Blisters comprised of PVdC coated PVC film and lacquered aluminum foil. Each blister strip contains 12 capsules. Four strips and a leaflet are packed into a cardboard 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 instructions.

7 MARKETING AUTHORISATION HOLDER

Nicobrevin (UK) Limited
Finsgate
5-7 Cranwood Street
London ECIV 9EE
England

8 MARKETING AUTHORISATION NUMBER

PA 0541/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 October 1990

Date of last renewal: 12 October 2000