Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vectarion 50 mg Film-coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of Almitrine Bismesylate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Film- coated tablets.

White, convex rod-shaped, tablets with a score mark on each surface.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Chronic obstructive lung disease and respiratory failure associated with hypoxaemia.

4.2 Posology and method of administration

Oral route.

The usual daily dose is 50 to 100 mg (1 to 2 tablets daily), divided into two doses. Absorption is improved if drug is taken with food. Balanced oxygen therapy may be administered simultaneously.

On the basis of experience to date it is recommended that after an initial 3 month treatment period, there should be an interval of one month without treatment. This can then be followed by a maintenance regime of two months on treatment and one month off treatment.

It is also recommended that the dose should be adjusted in relation to the patient's weight, the severity of the blood gas abnormality and the incidence of adverse reactions as follows:

Weight
For patients weighing less than 50 kg, the dose should be reduced to 1 tablet per day.

Blood gases
Occasionally the severity of the modification of these parameters warrants the dose to be increased to 3 or 4 tablets daily, but this should be undertaken for short periods of time only.

4.3 Contraindications

Use in patients hypersensitive to any of the active ingredients.

Use during pregnancy, or lactation in women breast-feeding infants.

Use in patients hypersensitive to any of the ingredients.

Use in patients with significant impairment of hepatic function.

4.4 Special warnings and precautions for use

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

Almitrine is of no value in the management of asthma, and should not be used in this condition since it may aggravate bronchospasm.

In the event of persisting paraesthesiae (prickling, formication, numbness and so on), it is advised to discontinue treatment.

Weight loss equal to or greater than 5% should lead to interruption of treatment.

Treatment with Vectarion should commence after evaluation of the patient by the appropriate specialist. The specialist should continue to have overall responsibility throughout treatment and should arrange periodic follow-up tests to monitor the patient's outcome.

Careful surveillance should be maintained on liver function during treatment particularly if used with other drugs dependent on intact hepatic function.

4.5 Interaction with other medicinal products and other forms of interaction

To date there is no evidence of potential interaction with other agents such as coumarin anti-coagulants, sulphonylurea hypoglycaemics.

4.6 Pregnancy and lactation

This product should not be used during pregnancy or lactation in women breast-feeding infants. Animal studies showed some foetotoxicity at high doses.

There have been no studies of use during pregnancy in human beings.

4.7 Effects on ability to drive and use machines

None Stated.

4.8 Undesirable effects

Weight loss, peripheral neuropathy with abnormal sensations or paraesthesia in the lower limbs (prickling, formication, numbness and so on). These effects are usually observed with long-term (1 year or more) treatment (see Special warnings and precautions for use).

Nausea, anorexia, sweating.

4.9 Overdose

No case of massive ingestion has been reported. Nevertheless, in cases of significant accidental overdosage, signs of hypocapnia with respiratory alkalosis may be observed.

Management
Symptomatic treatment of observed disorders with cardiorespiratory monitoring and repeated blood gas determination.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The drug improves PaO2 and PaCO2 through its effect on the ventilation/perfusion ratio.

5.2 Pharmacokinetic properties

The drug depends to a large extent on hepatobiliary routes for metabolism and excretion.

Almitrine is strongly protein bound.

5.3 Preclinical safety data

No finding in the preclinical testing which could be of relevance for the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Pregelatinised starch
Lactose Monohydrate
Povidone
Magnesium stearate
Talc

Coating

Beeswax, white
Titanium dioxide (E171)
Glycerol
Sodium laurilsulfate
Hypromellose
Macrogol 6000
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Two blister (PVC/Aluminum) per carton of 30 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

Servier Laboratories (Ireland) Ltd
First Floor, Block Two,
West Pier Business Campus
Old Dunleary Road
Dun Laoghaire
County Dublin.

8 MARKETING AUTHORISATION NUMBER

PA 0068/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 13th November 1984

Date of last renewal: 13th November 2004

10 DATE OF REVISION OF THE TEXT

November 2004