Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Opilon 40mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains moxisylyte hydrochloride 45.22 mg (equivalent to moxisylyte base 40 mg).

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
A round pale yellow film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Moxisylyte is an alpha-adrenergic blocking agent indicated for use in the treatment of peripheral vascular disorders and in the vasospastic conditions such as Raynaud's Phenomenon, and other such conditions where a peripheral vasodilator is required.

4.2 Posology and method of administration

Oral administration.

Adults:
One tablet to be swallowed four times a day. For those conditions affected by climatic environment, one tablet should be administered every three hours during the 12-hour period when symptoms are most likely to occur. In the event that a response is not evident within 2 weeks, the drug should be discontinued.

Elderly (over 65 years):
As for adults.

No clinical or pharmacokinetic data specific to this age group are available. However, at normal dosage no problems have been reported.

Children:
Opilon tablets are not indicated for use in children.

4.3 Contraindications

Opilon should not be given to patients who have suffered a recent cardiac infarction or are in the acute phase of a cerebrovascular accident or who have active liver disease. Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

The alpha-adrenergic blocking action of Opilon may potentiate the effect of a number of drugs used in the management

of hypertension. In practice, with the recommended dosage of Opilon, difficulties have not been reported.

Opilon should be used with caution in diabetes as, theoretically, insulin requirements may be reduced. Tricyclic antidepressants may increase any hypotensive effect produced by alpha blockade. Opilon should also be used with caution in patients with anginal symptoms and in patients who have suffered a recent cardiac infarction or in the presence of cerebrovascular insufficiency.

Hepatotoxicity, including hepatitis and cholestatic jaundice have been reported with moxisylyte use. This appears to be dose related and has occurred rarely at daily doses of 80 and 320mg and more frequently at higher doses. It is therefore recommended that liver function should be monitored periodically, especially if therapy is prolonged or if the higher range of the recommended dose is being used. Opilon should be withdrawn promptly if hepatic dysfunction develops.

Opilon tablets contain lactose, patients with rare hereditary problems, with galactose intolerance, the Lapp lactose deficiency or glucose – galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

See section 4.4 (Special Warnings and Precautions for Use).

4.6 Pregnancy and lactation

This product should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Vertigo has been reported with this product, if you feel dizzy or unwell you should not drive.

4.8 Undesirable effects

Occasionally, mild nausea, diarrhoea, vertigo, headache, facial flushing and rash may be encountered. These are, however, rare and transient. There have also been rare reports of hepatotoxicity, including cases of hepatitis and cholestatic jaundice, which are reversible on stopping treatment. Opilon should be withdrawn promptly if hepatic dysfunction develops.

4.9 Overdose

In overdosage, a fall in blood pressure is the main symptom. Nurse in head-down position. An iv infusion of noradrenaline may restore the blood pressure to normal, but expert advice should be sought.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Moxisylyte is an alpha-adrenergic blocking agent.

5.2 Pharmacokinetic properties

Moxisylyte is rapidly absorbed after oral administration. In plasma, the drug is rapidly converted to desacetylmoxisylyte (metabolite I) and desmethyldesacetylmoxisylyte (metabolite II) which are pharmacologically active. Other circulatory species are the sulphate and glucuronide conjugates of metabolites I and II. Excretion is almost exclusively via the kidneys. The half life of total radioactivity, after radio labelled moxisylyte was administered to man, was 1 to 2 hours.

5.3 Preclinical safety data

Pre-clinical safety data does not add anything of further significance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Colloidal silicon dioxide
Microcrystalline cellulose
Magnesium stearate
Maize starch
Hypromellose (E464)
Propylene glycol
Opaspray M-1-22900 Comprised of:
Titanium Dioxide (E171)
Hypromellose (E464)
Quinoline yellow (E104)
Ponceau 4R (E124)
Indigo Carmine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original container.

6.5 Nature and contents of container

a) Blister packs consisting of 250µ white opaque PVC blisters with 20µ aluminium foil backing in four strips of 30 tablets (120 tablets).

b) Blister packs consisting of 250µ white opaque PVC blisters with 20µ aluminium foil backing in four strips of 28 tablets (112 tablets).

Not all pack sizes may be marketed.

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

Link Pharmaceuticals Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 757/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 10 January 2005

10 DATE OF REVISION OF THE TEXT

March 2006