SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Flamingo Max Strength Congestion Relief 12.2 mg capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 12.2mg Phenylephrine Hydrochloride.

Excipients with known effect
Each capsule contains:
Lactose monohydrate 40.3 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard (capsule)

Size "3" hard gelatin capsule, yellow translucent cap & body, containing white to off-white granular powder or powder plug.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of nasal congestion, particularly when associated with colds and flu or hayfever.

4.2 Posology and method of administration

Adults and children 12 years and over: For oral use, one capsule, if necessary, up to four times daily.
The Elderly: Normal adult dosage is appropriate.
Children under 12 years: Not recommended.

4.3 Contraindications

Hypersensitivity to any of the ingredients. Avoid in patients with cardiovascular disease, hypertension, diabetes mellitus, closed angle glaucoma, hyperthyroidism, prostatic enlargement and phaeochromocytoma. Patients being treated with monoamine oxidase inhibitors or within 14 days of ceasing such treatment (see section 4.5).

4.4 Special warnings and precautions for use

This medicine should be used with caution in patients with occlusive vascular disease including Raynaud's phenomenon. Do not take for longer than 7 days, unless your doctor agrees.

This medicine contains 40.3 mg Lactose Monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

If symptoms do not go away seek a doctor’s advice.

Use with caution in patients with Raynaud’s phenomenon and diabetes mellitus. Patients with prostatic hypertrophy may have increased difficulty with micturition.

Sympathomimetic-containing products should be used with great care in patients suffering from angina.

Sympathomimetic-containing products may act as cerebral stimulants giving rise to insomnia, nervousness, and hyperpyrexia, tremor and epileptiform convulsions.

4.5 Interaction with other medicinal products and other forms of interaction

Should not be given to patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment. May enhance the

effects of anticholinergic drugs such as tricyclic antidepressants. May increase the possibility of arrhythmias in digitalised patients. May enhance the cardiovascular effects of other sympathomimetic amines (e.g. decongestants). This medicine should not be taken together with vasodilators, Beta-blockers or enzyme inducers such as alcohol.

4.6 Fertility, pregnancy and lactation

The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. In addition, because phenylephrine may reduce placental perfusion, the product should not be used in patients with a history of pre-eclampsia. In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Adverse effects may include tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting and headache. Urinary retention - this is more likely to occur in men with an enlarged prostate' (frequency not known).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of over dosage include irritability, restlessness, palpitations, hypertension, and difficulty in micturition, nausea, vomiting, thirst and convulsions. In severe over dosage gastric lavage and aspiration should be performed. Symptomatic and supportive measures should be undertaken, particularly with regard to cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta blocker may be required to control cardiac arrhythmias.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group (ATC classification)

R01BA03

Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha adrenergic activity and is without stimulating effects on the central nervous system. The sympathomimetic effect of phenylephrine produces vasoconstriction, which in turn relieves nasal congestion.

5.2 Pharmacokinetic properties

Phenylephrine is readily absorbed after oral administration but is subject to extensive pre systemic metabolism, much of which occurs in the enterocytes. As a consequence, systemic bioavailability is only about 40%. Following oral administration, peak plasma concentrations are achieved in 1-2 hours. The mean plasma half-life is in the range 2-3 hours. Penetration into the brain appears to be minimal.
Following absorption, the drug is extensively metabolised in the liver. Both phenylephrine and its metabolites are excreted in the urine.
The volume of distribution is between 200 and 500 litres, but there are no data on the extent of plasma protein binding.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (Spherolac 100)
Maize starch
Pregelatinised starch
Magnesium stearate

Hard Gelatin Capsules:
Gelatin,
Iron Oxide Yellow
Sodium laurilsulfate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

12 Months

6.4 Special precautions for storage

Do not store above 25° C. Store in the original packaging to protect from moisture.

6.5 Nature and contents of container

Aluminium- PVC/PVDC White Opaque Film blister packs of 12 Capsules.

6.6 Special precautions for disposal

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.
1st floor, Kirkland House,
11-15 Peterborough Road,
Harrow, Middlesex,
HA1 2AX, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0125

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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