

**MAX STRENGTH DECONGESTANT TABLETS
(PHENYLEPHRINE HYDROCHLORIDE)**

PL 16028/0114

UK Public Assessment Report

TABLE OF CONTENTS

Lay Summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 14
Summary of Product Characteristics	Page 15
Product Information Leaflet	Page 18
Labelling	Page 20

**MAX STRENGTH DECONGESTANT TABLETS
(PHENYLEPHRINE HYDROCHLORIDE)**

PL 16028/0114

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Galpharm Healthcare Limited a Marketing Authorisation (licence) for the medicinal product Max Strength Decongestant Tablets (PL 16028/0114) on 6th February 2008. This is a General Sales List medicine (GSL) used for the relief of nasal congestion.

Max Strength Decongestant Tablets contain the active ingredient, phenylephrine hydrochloride, which is a nasal decongestant and helps to open up the nasal airways allowing you to breathe more easily. The tablets are used to relieve a stuffy or blocked nose caused by colds and hayfever.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Max Strength Decongestant Tablets outweigh the risk; hence a Marketing Authorisation has been granted.

**MAX STRENGTH DECONGESTANT TABLETS
(PHENYLEPHRINE HYDROCHLORIDE)**

PL 16028/0114

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction	Page 4
Pharmaceutical assessment	Page 5
Preclinical assessment	Page 8
Clinical assessment	Page 9
Overall conclusion and risk benefit assessment	Page 13

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Galpharm Healthcare Limited a Marketing Authorisation for the medicinal product Max Strength Decongestant Tablets (PL 16028/0114) on 6th February 2008. This is a GSL medicine indicated for the treatment of nasal congestion.

The application was submitted as a standard national, abridged, bibliographic application, for an active of well-established use, according to Article 10(a) of Directive 2001/83/EC, as amended.

Each Max Strength Decongestant Tablet contains 12.2mg of the active ingredient, phenylephrine hydrochloride.

Phenylephrine hydrochloride (PE) is a post-synaptic α -receptor agonist, with low cardioselective β -receptor affinity. It has a recognised decongestant activity, by vasoconstriction, to reduce oedema of the nasal mucosa. α -adrenergic receptors are found on pre- and post-capillary blood vessels in the nasal mucosa, stimulation of which causes constriction of vascular smooth muscle. As a consequence, nasal blood flow is reduced leading to a reduction in nasal mucosal swelling. The tablets are indicated to relieve nasal congestion associated with colds and hayfever.

PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

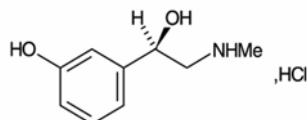
Phenylephrine hydrochloride

Nomenclature:

INN: Phenylephrine hydrochloride

Chemical name: (1R)-1-(3-hydroxyphenyl)-2-(methyl amino) ethanol hydrochloride

Structure:



Molecular formula: $C_9H_{13}NO_2$, HCl

Molecular weight: 203.7

CAS No: 61-76-7

Physical form: A white or almost white crystalline powder

Solubility: Freely soluble in water and ethanol

The active substance, phenylephrine hydrochloride, is the subject of a European Pharmacopoeia (EP) monograph.

All aspects of the manufacture and control of phenylephrine hydrochloride are supported by an EDQM Certificate of Suitability. This certificate is accepted as confirmation of the suitability of phenylephrine hydrochloride for inclusion in this medicinal product.

Appropriate stability data have been generated for phenylephrine hydrochloride stored in the proposed packaging. These data demonstrate the stability of the active substance and a suitable retest period has been set based on the data. The certificate of suitability confirms a retest period of 5 years if the material is stored at a temperature not exceeding 25°C in a container consisting of two polyethylene bags placed in a fibre drum or in a polyethylene bottle.

DRUG PRODUCT

Description & Composition

The drug product is presented as round, bi-convex, red film-coated tablets containing 12.18mg of the active substance phenylephrine hydrochloride.

Other ingredients consist of pharmaceutical excipients, namely lactose monohydrate, microcrystalline cellulose, powdered cellulose, magnesium stearate, sodium starch glycollate, and colloidal anhydrous silica making up the tablet core; titanium dioxide (E171), macrogol 4000, eudragit E 12.5, and hypromellose making up the film coating; and hypromellose, macrogol 4000, titanium dioxide, talc, azorubin, brilliant ponceau, red lake (E124), and polysorbate 80 making up the colour coating. Appropriate justification for the inclusion of each excipient has been provided.

All excipients used comply with their respective European Pharmacopoeia monographs, apart from azorubin, brilliant ponceau, and red lake (E124) which comply with EU guidelines. Satisfactory Certificates of Analysis have been provided for all excipients.

The magnesium stearate is of vegetable origin. The only excipient used that contains material of animal or human origin is lactose monohydrate. The applicant has provided a declaration that milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as milk collected for human consumption.

There were no novel excipients used and no overages.

Pharmaceutical development

Details of the pharmaceutical development of the drug product have been supplied and are satisfactory.

Manufacture

A description and flow-chart of the manufacturing method has been provided.

In-process controls have been provided and are appropriate considering the nature of the product and the method of manufacture. Process validation studies have been conducted and are satisfactory.

Finished product specification

The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of Analysis have been provided for any reference standards and working standards used.

Container Closure System

The tablets are packed in PVC (polyvinyl chloride) / PVDC (polyvinylidene chloride) / aluminium foil blisters, which are placed with the PIL into cardboard outer cartons. The product is packaged in carton pack sizes of 12 or 24 tablets.

Specifications and Certificates of Analysis for all packaging components used have been provided. These are satisfactory.

All primary product packaging complies with EU legislation, Directive 2002/72/EC (as amended), and is suitable for contact with foodstuffs.

Stability

Finished product stability studies have been conducted in accordance with current guidelines and results were within the proposed specification limits. Based on the results, a shelf-life of 2 years has been set, which is satisfactory. The storage instructions are 'Do not store above 25°C' and 'Store in the original package'.

Bioequivalence Study

There was no bioequivalence study carried out to support this application. The legal basis of the application is that it is bibliographic; therefore, a bioequivalence study is not required.

Expert Report

A satisfactory expert report is provided, and has been prepared by an appropriately qualified expert. An appropriate CV for the expert has been supplied.

Product Information

The approved SmPC, leaflet, and labelling are satisfactory.

Conclusion

All pharmaceutical issues have been resolved and the quality grounds for this application are considered adequate. A Marketing Authorisation may be granted.

PRECLINICAL ASSESSMENT

The application was submitted as a bibliographic application, for an active of well-established use, according to Article 10(a) of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

INDICATIONS

Max Strength Decongestant Tablets are indicated for the relief of nasal congestion associated with colds and hayfever.

The indication is consistent with other products containing phenylephrine hydrochloride as an active substance and is supported by the literature.

POSOLOGY AND METHOD OF ADMINISTRATION

Adults and children over 12 years: one tablet, up to four times daily.

Children under 12 years: not recommended

Elderly: There is no need for dosage reduction in the elderly.

The dose is appropriate.

TOXICOLOGY

No new data have been submitted and none are required for this type of application.

LEGAL STATUS

The legal status of the product is GSL. The current legal status of phenylephrine restricts the maximum single dose to 10mg as a general sale list product. 12.18 mg of phenylephrine hydrochloride is equivalent to 10mg of free phenylephrine and therefore the product falls within the current parameters for GSL status.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Phenylephrine is a post-synaptic α -receptor agonist, with low cardioselective β -receptor affinity. It has a recognised decongestant activity, by vasoconstriction to reduce oedema of the nasal mucosa.

No additional pharmacodynamic studies have been presented.

Pharmacokinetics

Phenylephrine has low bioavailability (~38%) from the gastrointestinal tract owing to variable absorption and first-pass metabolism. There is significant biotransformation in the intestinal wall. However, phenylephrine is active as a decongestant by the oral route, the drug distributes through the systemic circulation to the vascular bed of the nasal mucosa.

Bioequivalence Study

No bioequivalence studies have been conducted as the proposed product is indicated for the relief of symptoms in non-serious, self-limiting conditions and it is associated with a low incidence of serious adverse events at the dose proposed. The absence of a bioequivalence study is justified both in terms of the active substance and the medicinal product. Differences in bioavailability are unlikely to result in therapeutic inequivalencies.

EFFICACY

No new data are submitted and none are required for this type of application.

Phenylephrine is a decongestant which acts by vasoconstriction to reduce oedema and swelling of the nasal mucosa. By this means, nasal discharge may be reduced and obstruction associated with colds and influenza may be relieved. Despite the paucity of data on efficacy of oral phenylephrine, studies showing measurable reductions in nasal airway resistance have been provided. These data are sufficient for a product of this nature and demonstrates both activity and efficacy for its intended indications.

SAFETY

The applicant has not conducted safety studies in support of this submission. At sufficiently large doses; enough to result in nasal decongestion, phenylephrine has the potential to affect other vascular beds and exert a vasoconstrictor effect, therefore resulting in hypertension and bradycardia. This is because phenylephrine acts mainly as an α_1 -agonist and has only weak β -adrenoreceptor activity. The α_1 pressor action causes reflex bradycardia and therefore overall contractile force of the heart remains the same. Phenylephrine has little or no direct effect on the β_1 receptors in the heart which control heart rate, conduction velocity and contractile force and therefore arrhythmias are unlikely to occur following phenylephrine administration particularly at low dosage and over short treatment durations.

Adverse events are well characterised and correlate with the pharmacology of phenylephrine. Reports have included tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting, headache and urinary retention in men.

A Drug Analysis Print (DAP) was provided by the applicant covering a 42-year period from 01 July 1963 to 30 October 2005, during which time only 62 adverse drug reactions (ADRs) were attributed to single-ingredient phenylephrine products. The most frequently reported ADRs were categorised as: rhinitis (n = 6), drug dependence (n = 6), vomiting (n=3), malaise (n =3) nausea (n = 2), tachycardia (n= 2), dizziness (n = 2), rash (n =2), hypertension (n = 2). All other reported ADRs were singular events. No fatalities were reported during this period for single product phenylephrine. Three deaths were reported with multi-ingredient products, but the case reports were not available.

Large excesses of phenylephrine are required to cause increases in blood pressure; up to 120mg. 50mg of phenylephrine (5 tablets of the proposed product) as a single dose has been documented as the minimum amount required to cause an increase in blood pressure. 10mg phenylephrine was found not to affect blood pressure.

PE does not sedate or impair motor skills or coordination and is not known to affect the ability of consumers to drive or operate machinery. Effects on cognition are not significant.

Given the wide exposure of this product and the long history of use of oral phenylephrine, the safety record for phenylephrine is established, documented and reassuringly predictable. When used at recommended doses for short periods, phenylephrine hydrochloride 12.18 mg tablets are considered to be suitable for self-medication in order to treat the nasal congestion associated with the common cold and hayfever.

ABUSE AND MISUSE OF PHENYLEPHRINE

Abuse

Phenylephrine is much less readily converted to substances of abuse such as methamphetamine than other sympathomimetics such as pseudoephedrine. Phenylephrine differs from endogenous adrenaline in lacking a hydroxyl group in the 4-position. Because of its direct activity, it does not cause release of endogenous noradrenaline, and is therefore less likely to cause central nervous system stimulating effects such as restlessness, irritability, insomnia and anxiety. Although it is possible to convert phenylephrine to methamphetamine, it is a difficult process and would require much greater knowledge and equipment than the relatively simple conversion of pseudoephedrine to methamphetamine.

Published case reports of intentional and persistent abuse by determined individuals are very rare. Phenylephrine, at the recommended dose for phenylephrine hydrochloride 12.18 mg tablets, has no significant central nervous system stimulatory effects. Phenylephrine is an unlikely substance of recreational abuse. The potential for phenylephrine abuse using single-ingredient products such as phenylephrine hydrochloride 12.18 mg tablets is considered unlikely.

Misuse

Accidental misuse of this product is not reported by the applicant. There are a number of single and fixed dose combination phenylephrine products already available to the consumer and an associated, inherent risk of escalating doses of phenylephrine. This is less of an issue due to the wide safety window and high doses of phenylephrine required to cause unwanted effects. There are 6 reported cases of dependence, but data on these cases was not made available. Oral decongestants do not appear to cause rebound congestion, unlike topical products such as oxymetazoline. The maximum recommended duration of treatment is 7 days.

EXPERT REPORT

A satisfactory expert report is provided, and has been prepared by an appropriately qualified expert. An appropriate CV for the expert has been supplied.

PRODUCT INFORMATION:

Summary of Product Characteristics (SmPC)

The final SmPC is satisfactory.

Patient Information Leaflet (PIL)

The PIL is in line with the approved SmPC and is satisfactory.

Labelling

Colour mock-ups of the labelling have been provided. The labelling is satisfactory.

DISCUSSION AND CONCLUSION

This is a bibliographic application. No clinical study has been undertaken, or was necessary, to demonstrate the efficacy of the product. The bibliography is supportive of the efficacy of the active ingredient and provides adequate information regarding safety. Phenylephrine has been licensed for the treatment of nasal congestion for much more than 10 years and its well established use is accepted.

All issues have been adequately addressed by the applicant. Sufficient clinical information has been submitted to support this application. When used as indicated, Max Strength Decongestant Tablets have a favourable benefit-to-risk ratio. Therefore, a Marketing Authorisation may be granted on medical grounds.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Max Strength Decongestant Tablets are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

Single and repeat dose animal model data submitted is both limited and old (as far back as 1946), reflecting the historic nature of the active substance. The animal data appears consistent with effects seen in patients. There were no carcinogenic or mutagenic effects seen in animal models.

EFFICACY

No new data are submitted and none are required for this type of application.

Medicinal products containing phenylephrine have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

The published literature supports the efficacy of phenylephrine hydrochloride as a nasal decongestant and identifies no new safety issues or concerns. No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC, PIL and labelling are satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

The approved labelling artwork complies with statutory requirements. In line with current legislation, the name of the product in Braille appears on the outer packaging and sufficient space has been included for a standard UK pharmacy dispensing label.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with phenylephrine hydrochloride is considered to have demonstrated the therapeutic value of the active substance. The risk: benefit is, therefore, considered to be positive.

**MAX STRENGTH DECONGESTANT TABLETS
(PHENYLEPHRINE HYDROCHLORIDE)**

PL 16028/0114

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the marketing authorisation application on 18th June 2007
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 2nd August 2007
- 3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 29th August 2007
- 4 The applicant responded to the MHRA's request, providing further information for the quality sections on 8th November 2007
- 5 The application was determined on 6th February 2008

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Max Strength Decongestant Tablets is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Phenylephrine HCl 12.18 mg Tablets

Max Strength Decongestant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenylephrine Hydrochloride 12.18mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Round, bi-convex, red film coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of nasal congestion associated with colds and hayfever.

4.2 Posology and method of administration

Adults and children over 12 years: One tablet, up to four times daily.

Children under 12 years: Not recommended.

Elderly: There is no need for dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients. Avoid in patients with cardiovascular disease, high blood pressure, 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.

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

The label will state:

Do not take for more than 7 days, unless your doctor agrees.

If symptoms do not go away talk to your doctor.

Keep all medicines out of the reach and sight of children.

Warning: Do not exceed the stated dose.

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 or Beta-blockers.

4.6 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, headache and occasionally urinary retention in males.

4.9 Overdose

Symptoms of overdosage include irritability, restlessness, palpitations, hypertension, difficulty in micturition, nausea, vomiting, thirst and convulsions. In severe overdosage 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

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 presystemic 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 (DC)

Microcrystalline Cellulose

Powdered Cellulose

Magnesium stearate

Sodium starch glycollate (Type A)

Silica, colloidal anhydrous

Base coat (containing Macrogol 4000, Titanium dioxide E171, methacrylic acid-ethyl acrylate copolymer and Hypromellose)

Colour coat (containing Hypromellose, Macrogol 4000, Talc, Azorubin E122, Brilliant Ponceau E124, Red lake E 124, Polysorbate 80)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Phenylephrine Hydrochloride tablets are packed into PVC/ PVdC/ Aluminium foil blisters. Each blister consists of 12 red film coated tablets.

Pack sizes: 12 or 24 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Ltd,
Hugh House,
Upper Cliffe Road
Dodworth Business Park
Dodworth
Barnsley
South Yorkshire
S75 3SP

8 MARKETING AUTHORISATION NUMBER(S)

PL 16028/0114

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/02/2008

10 DATE OF REVISION OF THE TEXT

06/02/2008

PATIENT INFORMATION LEAFLET

Max Strength Decongestant Tablets Phenylephrine hydrochloride

PATIENT INFORMATION LEAFLET

Read this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.

IN THIS LEAFLET:

1. What this medicine is for
2. Before you take the medicine
3. How to take the medicine
4. Possible side effects
5. Storing the medicine
6. Further information

1 WHAT THIS MEDICINE IS FOR

Phenylephrine hydrochloride is a nasal decongestant. It reduces the blood vessels in the nose and sinuses which opens the nasal airways helping you to breathe more easily.

Max Strength Decongestant Tablets contain phenylephrine hydrochloride and are used to relieve a stuffy or blocked nose caused by colds and hayfever.

2 BEFORE YOU TAKE THE MEDICINE

Do not take Max Strength Decongestant Tablets if you:

- are allergic to phenylephrine hydrochloride or any of the other ingredients listed in section 6
- have heart problems or high blood pressure (particularly due to a tumour near the kidney)
- have diabetes
- have prostate problems
- have glaucoma (increased pressure in the eye)
- have an overactive thyroid gland
- are taking Monoamine Oxidase inhibitor medicines (used for depression) or have taken them within the last 14 days
- are pregnant or breast feeding.

Talk to your doctor or pharmacist before taking this medicine if you:

- have problems with your blood circulation (including Raynaud's Phenomenon, which makes the toes and fingers numb and pale).

If you are taking other medicines

You must not take these tablets if you are taking:

- Monoamine Oxidase inhibitor medicines (used for depression) or have taken them within the last 14 days.

Talk to your pharmacist or doctor before you take the tablets if you are using any of the following medicines:

- any heart medicines (especially digoxin)
- drugs for helping blood circulation and controlling angina (such as glyceryl trinitrate)
- beta-blockers (e.g. atenolol)
- tricyclic antidepressants (e.g. amitriptyline)
- some antibiotics
- some epilepsy treatments
- other nasal decongestants.

Pregnancy and Breast feeding

Do not take the tablets if you are pregnant or breast feeding.

Important information about some of the ingredients

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

3 HOW TO TAKE THE MEDICINE

Age	Dose and how often to take
Adults, the elderly and children aged 12 years and over.	Take 1 tablet up to four times a day as required. Swallow the tablet with a glass of water. Leave at least 4 hours between doses. Do not take more than 4 tablets in 24 hours.
If symptoms do not go away talk to your doctor. Do not take for more than 7 days unless your doctor agrees. Do not exceed the stated dose.	
Do not give to children under 12 years.	

If you take too many tablets: Talk to a doctor straight away, or go to your nearest hospital casualty department. Take the carton and this leaflet with you.

4 POSSIBLE SIDE EFFECTS

Most people take Max Strength Decongestant Tablets without any problems, but they can have side effects, like all medicines.

If you experience any of the following symptoms, or have any other unusual symptoms or concerns with your medicine, stop taking the tablets and talk to your pharmacist or doctor:

- fast heart rate, changes in heart rhythm, palpitations (feeling your heartbeat), high blood pressure
- feeling sick, vomiting
- headache
- men may have difficulty passing urine.

5 STORING THE MEDICINE

Do not use after the expiry date shown on the carton or blister.

Do not store above 25°C. Store in the original container.

Keep all medicines out of the reach and sight of children.

6 FURTHER INFORMATION**What is in this medicine:**

The active ingredient is: Phenylephrine hydrochloride 12.2 mg in each tablet.

The other ingredients are: Lactose monohydrate, cellulose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica, macrogol 4000, methacrylic acid-ethyl acrylate copolymer, talc, hypromellose, polysorbate 80. Colourings are titanium dioxide (E171), azorubin (E122), ponceau 4R (E124), red lake (E124).

What this medicine looks like and contents of the pack

Max Strength Decongestant Tablets are round red film coated tablets.

- This pack contains 12 or 24 tablets.

- **Marketing Authorisation Holder:** Galpharm Healthcare Ltd, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire S76 3SP

- **Manufacturer:** Lomapharm, Langes Feld 5, 31860 Emmerthal, Germany

Date of approval: MM/YYYY

LABELLING

Carton for blisters



Generic packaging

Carton for blisters



Carton showing braille only

