# LORATADINE 5MG/5ML SYRUP
# PL 04917/0067

## UKPAR

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# LORATADINE 5MG/5ML SYRUP
# PL 04917/0067

## LAY SUMMARY

The MHRA has granted Pinewood Laboratories Limited a Marketing Authorisation (licence) for the medicinal product Loratadine 5mg/5ml Syrup (PL 04917/0067). This is available to the general public and healthcare professionals to relieve the symptoms of hayfever (such as runny nose, sneezing and burning/itchy eyes) and skin allergies (such as rash, itching or hives).

Loratadine Syrup contains the active ingredient loratadine, which belongs to a group of medicines known as antihistamines. These can be used to relieve the symptoms of allergic reactions.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Loratadine 5mg/5ml Syrup outweigh the risks, hence a Marketing Authorisation has been granted.

# LORATADINE 5MG/5ML SYRUP
# PL 04917/0067

## SCIENTIFIC DISCUSSION

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# INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product Loratadine 5mg/5ml Syrup (PL 04917/0067) on 14th November 2006. The product is available to the general public and healthcare professionals (legal status P).

This is an application for Loratadine Syrup (5mg/5ml), submitted as an abridged application according to Article 10.1 of Directive 2001/83/EC, claiming essential similarity to the innovator product Clarityn Syrup (Schering Plough Limited, UK).

The product contains the active ingredient loratadine, a second-generation antihistamine. This long-acting tricyclic antihistamine has a selective H1-receptor antagonist activity. Loratadine 5mg/5ml Syrup is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

No clinical trials have been performed. This is consistent with the current guidelines relating to bioequivalence/bioavailability for such preparations, where it is considered that the excipients will not interfere with bioavailability of the drug. In this instance there are no concerns as the same excipients are used in this formulation compared to that of the innovator product (Clarityn Syrup).

# PHARMACEUTICAL ASSESSMENT

## DRUG SUBSTANCE

### Loratadine

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance loratadine.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data are provided and comply with the proposed specification.

## DRUG PRODUCT

### Other ingredients

Other ingredients consist of pharmaceutical excipients, namely propylene glycol, glycerol, sodium benzoate (E211), citric acid monohydrate, sucrose, purified water and peach flavouring. All excipients used comply with their respective European Pharmacopoeia monograph, with the exception of peach flavouring (which is in compliance with a satisfactory in-house specification). Satisfactory certificates of analysis have been provided for all excipients.

Glycerol is prepared from tallow, however, sufficient information has been provided by the applicant to show that glycerol from this source is suitable for use and any risk from TSE is minimised.

### Manufacture

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

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out and the results appear satisfactory.

### Finished product specification

The finished product specification is satisfactory. 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 working standards used.

### Container Closure System

Specifications and Certificates of Analysis for the packaging material have been provided. These are satisfactory. The applicant has provided confirmation that all primary packaging materials used comply with relevant EU Directives concerning contact of materials with foodstuff.

## Stability

Finished product stability studies have been conducted on pilot-scale validation batches in accordance with current guidelines. Based on the results, a shelf-life of 24 months has been set (which is reduced to 6 months after opening), which is satisfactory. No storage conditions are stipulated.

Suitable post-approval commitments have been made for stability testing on production-scale batches.

## Conclusion

It is recommended that a Marketing Authorisation is granted for this application.

The requirements for essential similarity of the proposed and original product have been met with respect to qualitative and quantitative content.

# PRECLINICAL ASSESSMENT

This application for a generic product claims essential similarity to Clarityn Syrup (Schering Plough Limited, UK), which have been licensed within the EEA for over 10 years.

No new preclinical data have been supplied with these applications and none are required for an application of this type.

# CLINICAL ASSESSMENT

## CLINICAL PHARMACOLOGY

This application does not require the inclusion of a bioequivalence study as it is an application claiming essential similarity for a liquid oral form of the drug containing the same active substance in the same concentration as the reference product, and does not contain any excipients that will affect absorption.

## EFFICACY

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

## SAFETY

No formal safety data are presented. The adverse events that can be expected are listed in the SPC and are consistent with those for the reference product.

## CLINICAL OVERVIEW

There is a clinical expert report from a consultant to the pharmaceutical industry. The expert concludes that loratadine is safe and efficacious with regard to the proposed use and indications stated in the summary of product characteristics, provided the stated precautions and warnings are followed.

## SUMMARY OF PRODUCT CHARACTERISTICS

This is consistent with the reference product and is satisfactory.

## LABELLING

This is satisfactory.

## MAA FORM

The MAA is satisfactory.

## DISCUSSION

The data presented has shown that Loratadine 5mg/5ml Syrup is essentially similar to Clarityn 1mg/ml Syrup.

## RECOMMENDATIONS

It is recommended that a marketing authorisation is granted for this product.

## OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

### QUALITY

The important quality characteristics of Loratadine 5mg/5ml Syrup 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 applications of this type.

### EFFICACY

This application does not require the inclusion of a bioequivalence study as it is an application claiming essential similarity for a liquid oral form of the drug containing the same active substance in the same concentration as the reference product, and does not contain any excipients that will affect absorption. Thus, essential similarity is assumed on this basis.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for Clarityn 1mg/ml Syrup.

### RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The nature of the application means that essential similarity can be inferred by the fact that the product has the same concentration of active substance and does not contain any excipients that would affect absorption. Extensive clinical experience with loratadine is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

# LORATADINE 5MG/5ML SYRUP
# PL 04917/0067

## STEPS TAKEN FOR ASSESMENT

| | |
|---|---|
| 1 | The MHRA received the marketing authorisation application on 27th October 2003 |
| 2 | Following standard checks and communication with the applicant the MHRA considered the application valid on 26th November 2003 |
| 3 | Following assessment of the application the MHRA requested further information relating to the clinical dossiers on 25th February 2004 and 6th May 2005, and further information relating to the quality dossiers on 19th April 2004, 6th May 2005 and 31st January 2006. |
| 4 | The applicant responded to the MHRA's requests, providing further information on 26th January 2005 and 22nd November 2005 for the clinical sections, and again on 26th January 2005, 22nd November 2005 and 1st February 2006 for the quality sections. |
| 5 | The application was determined on 14th November 2006 |

# LORATADINE 5MG/5ML SYRUP
# PL 04917/0067

## STEPS TAKEN AFTER AUTHORISATION - SUMMARY

| Date submitted | Application type | Scope | Outcome |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Loratadine 5 mg/5 ml Syrup

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of syrup contains 1mg loratadine.
Each 1 ml of syrup also contains the following excipients:
0.11 g glycerol (E422)
0.11 g propylene glycol
0.6 g sucrose

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral Solution
Colour free, Peach flavour

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Loratadine 5mg/5ml Syrup is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

### 4.2 Posology and method of administration

For oral administration

Adults and children over 12 years of age: 10ml (10mg) of the syrup once daily.

Children 2 to 12 years of age with:
Body weight more than 30kg: 10ml (10mg) of the syrup once daily;
Body weight 30kg or less: 5ml (5mg) of the syrup once daily.

Efficacy and safety of Loratadine 5mg/5ml Syrup in children under 2 years of age has not been established.

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine. An initial dose of 10mg every other day is recommended for adults and children weighing more than 30kg, and for children weighing 30kg or less, 5ml (5mg) every other day is recommended.

No dosage adjustments are required in the elderly or in patients with renal insufficiency.

### 4.3 Contraindications

Loratadine 5mg/5ml Syrup is contraindicated in patients who are hypersensitive to the active substance or to any of the excipients in this formulation.

## 4.4 Special warnings and precautions for use

Loratadine 5mg/5ml Syrup should be administered with caution in patients with severe liver impairment (see section 4.2).

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The administration of Loratadine 5mg/5ml Syrup should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

## 4.5 Interaction with other medicinal products and other forms of interaction

When administered concomitantly with alcohol, Loratadine 5mg/5ml Syrup has no potentiating effects as measured by psychomotor performance studies.

Due to the wide therapeutic index of loratadine no clinically relevant interactions are expected and none were observed in the conducted clinical trials (see section 5.2).

## 4.6 Pregnancy and lactation

Loratadine was not teratogenic in animal studies. The safe use of loratadine during pregnancy has not been established. The use of Loratadine 5mg/5ml Syrup during pregnancy is therefore hot recommended.

Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women.

## 4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

## 4.8 Undesirable effects

In clinical trials in a paediatric population children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).

In clinical trials involving adults and adolescents in a range of indications including AR and CIU, at the recommended dose of 10mg daily, adverse reactions with loratadine were reported in 2% of patients in excess of those treated with the placebo. The most frequent adverse reactions reported in excess of placebo were somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1%). Other adverse reactions reported very rarely during the post-marketing period are listed in the following table:

| | |
|---|---|
| Immune disorders | Anaphylaxis |
| Nervous system disorders | Dizziness |
| Cardiac disorders | Tachycardia, palpitation |
| Gastrointestinal disorders | Nausea, dry mouth, gastritis |
| Hepato-biliary disorders | Abnormal hepatic function |
| Skin and subcutaneous tissue disorders | Rash, alopecia |
| General disorders and administration site conditions | Fatigue |

**4.9 Overdose**

Overdosage with loratadine increased the occurance of anticholinergic symptoms. Somnolence, tachycardia, and headache have been reported with overdoses.

In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long as necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: anti histamines – H1 antagonist, ATC code: R06A X13.

Loratadine, the active ingredient in Loratadine 5mg/5ml Syrup, is a tricyclic antihistamine with selective, peripheral H1-receptor activity.

Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage. During long-term treatment there were no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms.

Loratadine has no significant H2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.

**5.2 Pharmacokinetic properties**

After oral administration, loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite-desloratadine (DL)- is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations ($T_{max}$) between 1-1.5 hours and 1.5-3.7 hours after administration, respectively.

Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in

controlled trials, but without clinically significant changes (including electrocardiographic).

Loratadine is highly bound (97% to 99%) and its active metabolite moderately bound (73% to 76%) to plasma proteins.

In healthy subjects, plasma distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours, respectively. The mean elimination half lives in healthy adult subjects were 8.4 hours (range=3 to 20 hours) for loratadine and 28 hours (range-8.8 to 92 hours for the major active metabolite).

Approximately 40% of the dose is excreted in the urine and 42%in the faeces over a 10 day period and mainly in the form of conjugated metabolites. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. Less than 1% of the active substance is excreted unchanged in active form, as loratadine or DL.

The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

The pharmacokinetic profile of loratadine and its metabolites is comparable in healthy adult volunteers and in healthy geriatric volunteers.

Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect.

In patients with chronic renal impairment, both the AUC and peak plasma levels ($C_{max}$) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels ($C_{max}$) of patients with normal renal function. The mean elimination half-lives of loratadine and its metabolite were not significantly different form that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.

In patients with chronic alcoholic liver disease, the AUC and peak plasma levels ($C_{max}$) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

Loratadine and its active metabolite are excreted in the breast milk of lactating women.

## 5.3 Preclinical safety data

Preclinical data reveal no special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels (AUC) 10 times higher than those achieved with clinical doses.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Propylene glycol
Glycerol (E422)
Sodium Benzoate (E211)
Citric Acid Monohydrate
Sucrose
Purified Water
Peach Flavour

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

Bottle made from Type III Amber Glass with a tamper evident child resistant closure having a polypropylene outer layer and a polyethylene inner layer. This product is provided with a measuring device.

Pack Sizes: 60 ml, 100 ml and 150 ml.

### 6.6 Special precautions for disposal

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited trading as Pinewood Healthcare
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 04917/0067

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/11/2006

## 10 DATE OF REVISION OF THE TEXT

14/11/2006

# PATIENT INFORMATION LEAFLET

## PATIENT INFORMATION LEAFLET
## Loratadine 5 mg/5 ml Syrup

**Please read this leaflet carefully before you start to take this medicine.**
*This medicine is available without prescription, for you to treat a mild illness without a doctor's help. Nevertheless, you still need to use Loratadine 5 mg/5 ml Syrup carefully to get the best results from it.*

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

**In this leaflet:**



The name of your medicine is Loratadine 5 mg/5 ml Syrup. It is a colour free peach flavoured syrup.

- **The active substance is:** Loratadine
- **Other ingredients:** propylene glycol, glycerol (E422), sodium benzoate (E211), citric acid monohydrate, sucrose, peach flavour and purified water.

**Marketing Authorisation Holder and Manufacturer:**
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
**Product Licence number:** PL 04917/0067

### 1. What Loratadine 5 mg/5 ml Syrup is and what it is used for

- This medicine belongs to a group of medicines called antihistamines
- The product is presented in pack sizes of 60 ml, 100 ml and 150 ml; not all pack sizes may be marketed.

Loratadine 5 mg/5 ml Syrup is used in both adults and children over 2 years of age to relieve the symptoms of hayfever such as sneezing, runny nose and burning, itchy eyes. It may also be used for skin allergies such as rash, itching or urticaria (hives).

### 2. Before you take/use Loratadine 5 mg/5 ml Syrup

Do not take/use Loratadine 5 mg/5 ml Syrup

- If you or your child are hypersensitive (have had a bad reaction to) to any of the ingredients in this medicine.
- If you are pregnant, planning to become pregnant or are breast-feeding.

Consult your doctor if you:

- Have had an allergic reaction to antihistamines in the past.
- If you have severe liver impediment.

**Driving and using machines:**
Loratadine very rarely causes drowsiness at the recommended dosage. However, individuals react differently so if affected, do not drive or operate machinery.

**Important information about some of the ingredients of Loratadine 5 mg/5 ml Syrup**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**Taking/using other medicines**
Please consult your doctor or pharmacist if you are taking, or have recently taken, any other medicine - even those not prescribed, especially:-

- cimetidine (for stomach problems)
- erythromycin (an antibiotic)
- ketoconazole or fluconazole (for fungal infections)
- quinidine (for heart problems)
- fluoxetine (for depression)

Antihistamines may prevent response to allergens in skin allergy testing, therefore this medicine should be stopped four days prior to such testing.

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**3. How to take/use Loratadine 5 mg/5 ml Syrup**
For oral use only. Shake the bottle well before use. Use the measuring device provided. Each spoonful is a 5 ml dose.

| | |
|---|---|
| Adults & Children over 12 years of age: | 10 ml (10 mg) of the syrup once daily |
| Children 2 to 12 years of age with: | |
| Body weight more than 30 kg | 10 ml (10 mg) of the syrup once daily |
| Body weight 30 kg or less | 5 ml (5 mg) of the syrup once daily |

**Do not exceed the stated dose.**

If you have the impression that Loratadine 5 mg/5 ml Syrup is too strong or too weak, talk to your doctor or pharmacist.

**If you take/use more Loratadine 5 mg/5 ml Syrup than you should**
If you may have taken/used more Loratadine 5 mg/5 ml Syrup than you should, talk to a doctor or pharmacist immediately. Overdose may cause mild drowsiness.

**If you forget to take Loratadine 5 mg/5 ml Syrup**
If you forget to take a dose, take it as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to make up for forgotten individual doses.

**4. Possible Side Effects**
Like all medicines, Loratadine 5 mg/5 ml Syrup can have side effects.
If any of the following happen, stop taking Loratadine 5 mg/5 ml Syrup and tell your doctor immediately or go to the casualty department at your nearest hospital:
- severe allergic reaction (swelling of the face, mouth, lips or throat).

Tell your doctor as soon as possible if you notice any of the following:
- loss of hair
- liver problems
- disturbances in heart rhythm
- fainting
- fatigue
- headache
- nausea

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**5. Storing Loratadine 5 mg/5 ml Syrup**
There are no special storage instructions. Keep this medicine out of the reach and sight of children.
Shelf life after opening - 6 months.

**Use by date:** Do not use this medicine after the expiry date shown on the label.

Do not use Loratadine 5 mg/5 ml Syrup if you notice any defects or signs of deterioration. If unsure consult your pharmacist before taking. Return all unused medicines to your pharmacist for safe disposal.

**This leaflet was approved:**
**This leaflet was updated:** April 2006.

PINEWOOD
HEALTHCARE
Clonmel, Ireland.

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## LABELS


100 ml
Peach Flavour
Loratadine
5 mg/5 ml Syrup
Allergy relief for adults
& children over 2 years
Colour Free
PINEWOOD
HEALTHCARE
Clonmel, Ireland.
Each 5 ml of syrup contains 5 mg of the active Loratadine. Also includes propylene glycol, glycerol and sucrose. Loratadine provides relief in adults and children over 2 years of age from the symptoms of hayfever such as sneezing, runny nose and burning, itchy eyes. It may also be used for skin allergies such as rash, itching or urticaria (hives).
Do not use Loratadine 5 mg/5 ml Syrup if you are allergic to any of the ingredients or are pregnant or breast-feeding. Loratadine 5 mg/5 ml Syrup should be administered with caution in patients with severe liver impairment. If symptoms persist consult your doctor.
Directions: Please read the patient information leaflet carefully before use. Shake the bottle well before use. Use measuring device provided.
Dosage: (1 spoonful = 5 ml)
Adults & Children over 12 years of age: 10 ml (10 mg) of the syrup once daily
Children 2 to 12 years of age with:
Body weight more than 30 kg: 10 ml (10 mg) of the syrup once daily
Body weight 30 kg or less: 5 ml (5 mg) of the syrup once daily
Do not exceed the stated dose.
As with all medicines, talk to your doctor or pharmacist if you or your child are taking any other medicines.
Keep all medicines out of the reach and sight of children.
There are no special storage instructions.
Shelf life after opening - 6 months.
Marketing Authorisation Holder/Manufacturer:
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
PL 04917/0067
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3PC
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B/N:
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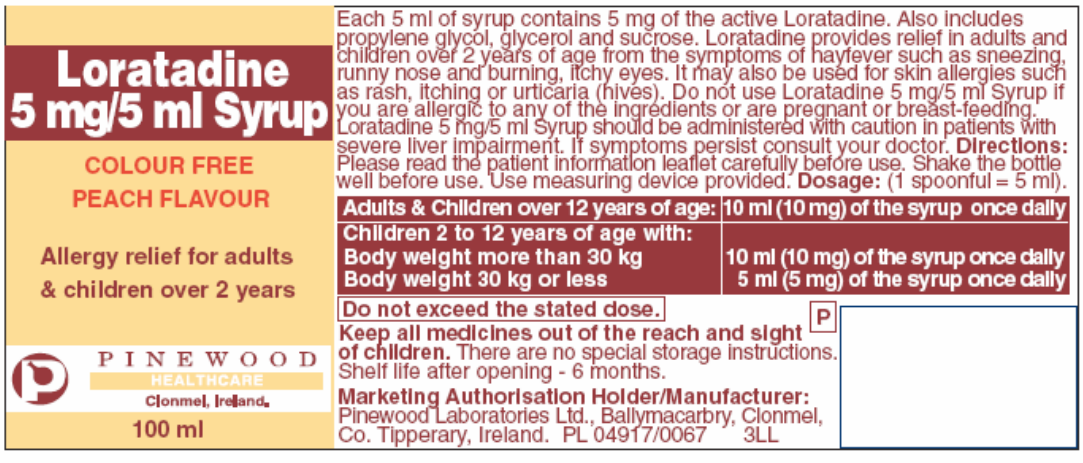
Loratadine
5 mg/5 ml Syrup
COLOUR FREE
PEACH FLAVOUR
Allergy relief for adults
& children over 2 years
PINEWOOD
HEALTHCARE
Clonmel, Ireland.
100 ml
Each 5 ml of syrup contains 5 mg of the active Loratadine. Also includes propylene glycol, glycerol and sucrose. Loratadine provides relief in adults and children over 2 years of age from the symptoms of hayfever such as sneezing, runny nose and burning, itchy eyes. It may also be used for skin allergies such as rash, itching or urticaria (hives). Do not use Loratadine 5 mg/5 ml Syrup if you are allergic to any of the ingredients or are pregnant or breast-feeding. Loratadine 5 mg/5 ml Syrup should be administered with caution in patients with severe liver impairment. If symptoms persist consult your doctor. Directions: Please read the patient information leaflet carefully before use. Shake the bottle well before use. Use measuring device provided. Dosage: (1 spoonful = 5 ml).
Adults & Children over 12 years of age: 10 ml (10 mg) of the syrup once daily
Children 2 to 12 years of age with:
Body weight more than 30 kg: 10 ml (10 mg) of the syrup once daily
Body weight 30 kg or less: 5 ml (5 mg) of the syrup once daily
Do not exceed the stated dose.
P
Keep all medicines out of the reach and sight of children. There are no special storage instructions. Shelf life after opening - 6 months.
Marketing Authorisation Holder/Manufacturer:
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0067 3LL


**Loratadine 5 mg/5 ml Syrup**

COLOUR FREE

PEACH FLAVOUR

Allergy relief for adults & children over 2 years

PINEWOOD HEALTHCARE Clonmel, Ireland.

150 ml

Each 5 ml of syrup contains 5 mg of the active Loratadine. Also includes propylene glycol, glycerol and sucrose. Loratadine provides relief in adults and children over 2 years of age from the symptoms of hayfever such as sneezing, runny nose and burning, itchy eyes. It may also be used for skin allergies such as rash, itching or urticaria (hives). Do not use Loratadine 5 mg/5 ml Syrup if you are allergic to any of the ingredients or are pregnant or breast-feeding. Loratadine 5 mg/5 ml Syrup should be administered with caution in patients with severe liver impairment. If symptoms persist consult your doctor. **Directions:** Please read the patient information leaflet carefully before use. Shake the bottle well before use. Use measuring device provided. **Dosage:** (1 spoonful = 5 ml).

| | |
|---|---|
| **Adults & Children over 12 years of age:** | **10 ml (10 mg) of the syrup once daily** |
| **Children 2 to 12 years of age with:** | |
| **Body weight more than 30 kg** | **10 ml (10 mg) of the syrup once daily** |
| **Body weight 30 kg or less** | **5 ml (5 mg) of the syrup once daily** |

P

Do not exceed the stated dose.

**Keep all medicines out of the reach and sight of children.**
There are no special storage instructions.
Shelf life after opening - 6 months.

**Marketing Authorisation Holder/Manufacturer:**
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0067 3LL