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LORATADINE 5MG/5ML ORAL SOLUTION

PL 33410/0067

LAY SUMMARY

The MHRA granted APSLA Limited a Marketing Authorisation (licence) for the medicinal product Loratadine 5mg/5ml Oral Solution on 31 March 2011. This pharmacy-only medicine (P) is used both in adults and children over 2 years of age to relieve the symptoms of hayfever (such as sneezing, runny nose and burning, itchy eyes) and skin allergies (such as rash, itching or hives).

Loratadine 5mg/5ml Oral Solution contains the active substance loratadine, which belongs to a group of medicines known as anti-histamines.

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

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Introduction ........................................ Page 4
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Non-clinical assessment ..................... Page 7
Clinical assessment .......................... Page 8
Overall conclusions and risk benefit assessment Page 9
Based on the review of the data on quality, safety and efficacy, the MHRA granted APSLA Limited, a Marketing Authorisation for the medicinal product Loratadine 5mg/5ml Oral Solution (PL 33410/0067) on 31 March 2011. This pharmacy-only medicines (P) is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

This is a standard abridged application submitted under Article 10(1) of Directive 2001/83/EC, as amended claiming to be a generic medicinal product of Clarityn® 1mg/1ml Syrup (PL 00201/0173) granted to Schering Plough Ltd, UK on 16 March 1992.

This product contains the active ingredient loratadine which belongs to a group of medicines called ‘other antihistamines for systemic use’ (ATC code R06AX13). Loratadine is a long-acting antihistamine agent, exhibiting partial selectivity for peripheral histamine H\textsubscript{1}-receptors.

No new non-clinical data have been submitted, which is acceptable given that the application was based on being a generic medicinal product of an originator product that has been in clinical use for over 10 years.

No new clinical studies were conducted, which is acceptable given that the application was based on being a generic medicinal product of an originator product that has been licensed for over 10 years.

The MHRA considers that the Pharmacovigilance System as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country. A suitable justification has been provided for the non-submission of a Risk Management Plan.

No new or unexpected safety concerns were raised during the assessment of this application and it was, therefore, judged that the benefits of taking Loratadine 5mg/5ml Oral Solution outweigh the risks; hence a Marketing Authorisation has been granted.
**PHARMACEUTICAL ASSESSMENT**

**ACTIVE SUBSTANCE**

INN: Loratadine


Structure:

![Chemical Structure Image]

Molecular formula: $\text{C}_{22}\text{H}_{23}\text{ClN}_{2}\text{O}_{2}$

Molecular weight: 382.9

Description: White or almost white crystalline powder.

Solubility: Practically insoluble in water, freely soluble in acetone and methanol.

Loratadine is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance loratadine are covered by a European Directorate for the Quality of Medicines (EDQM) Certificate of Suitability.

**MEDICINAL PRODUCT**

**Other ingredients**

Other ingredients consist of pharmaceutical excipients, namely propylene glycol (E1520), sodium benzoate (E211), disodium edentate, maltitol (Lycasin 80/55) (E965), glycerol (E422), citric acid monohydrate, menthol, Flavour Peach 193421 and sucralose (E955).

Appropriate justification for the inclusion of each excipient has been provided.

All excipients used comply with their respective European Pharmacopoeia monograph with the exception of Flavour Peach 193421, which is compliant with suitable in-house specifications and sucralose which complies with National Formulary specifications. Satisfactory Certificates of Analysis have been provided for all excipients. The natural flavouring substances used in the menthol and peach flavouring conform to Directive 88/388/EEC, concerning food additives and flavouring.

None of the excipients are of animal or human origin. No genetically modified organisms (GMO) have been used in the preparation of these excipients.

**Pharmaceutical development**

The aim of the development programme was to formulate a safe, efficacious, stable product that could be considered a generic medicinal product of Clarityn® 1mg/1ml Syrup (Schering Plough Ltd, UK).

Suitable pharmaceutical development data have been provided for this application.
Manufacture
A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulae have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

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 any working standards used.

Container Closure System
The product is available in pack sizes of 100ml and packaged in the following container presentations:
1. Amber coloured transparent polyethylene terphthalate (PET) bottles with a 28mm polypropylene (PP) tamper proof child resistance cap
2. Amber coloured round glass bottles with a 28 mm polypropylene (PP) tamper proof child resistance cap.

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 3 years for the unopened container with no special storage conditions is set and is acceptable. The shelf life after first opening the container is 3 months.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labelling
The SmPC, PIL and labelling are pharmaceutically 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, as amended. 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.

MAA Form
The MAA form is pharmaceutically satisfactory.

Expert Report
A quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

Conclusion
It is recommended that a marketing authorisation is granted for this application.
NON-CLINICAL ASSESSMENT

PHARMACODYNAMICS, PHARMACOKINETICS AND TOXICOLOGY
No new non-clinical data were submitted, which is acceptable given that the proposed product is a generic medicinal product of an originator product that has been licensed for over 10 years.

NON-CLINICAL EXPERT REPORT
The non-clinical overview has been written by an appropriately qualified person and is a suitable summary of the non-clinical aspects of the dossier.

ENVIRONMENTAL RISK ASSESSMENT
A suitable justification has been provided for non-submission of an Environmental Risk Assessment. As this product is intended for generic substitution with a product that is already marketed, no increase in environmental burden is anticipated. Thus, the justification for non-submission of an Environmental Risk Assessment is accepted.

CONCLUSION
It is recommended that a marketing authorisation is granted for this application.
CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY
Pharmacokinetics
In accordance with Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98), a bioequivalence study is not requested if the product is to be administered as an oral solution and contains the same active substance in the same concentration as the currently licensed product.

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

SAFETY
No new safety data were submitted and none were required for this application.

EXPERT REPORT
A clinical overview has been written by an appropriately qualified person and is a suitable summary of the clinical aspects of the dossier.

Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), Labels
The SmPC, PIL and labels are medically acceptable. The SmPC is consistent with that for the originator product. The PIL is consistent with the SmPC and in-line with current guidelines. The labelling is in-line with current guidelines.

PRODUCT INFORMATION:
Summary of Product Characteristics (SmPC)
The SmPC is clinically satisfactory and is consistent with that for the reference product.

Patient Information Leaflet (PIL)
The PIL is satisfactory and consistent with the SmPC.

Labelling
The labelling is satisfactory.

CONCLUSION
There are no objections to the approval of this application from a clinical viewpoint.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The important quality characteristics of Loratadine 5mg/5ml Oral Solution 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.

NON-CLINICAL
No new non-clinical data were submitted. As the pharmacokinetics, pharmacodynamics and toxicology of loratadine are well-known, no additional data were required.

EFFICACY
No new efficacy data were submitted and none were required for this application.

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC, PIL and labelling are satisfactory and consistent with those for the reference product.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with loratadine is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is, therefore, considered to be positive.
LORATADINE 5MG/5ML ORAL SOLUTION

PL 33410/0067

STEPS TAKEN FOR ASSESSMENT

1  The MHRA received the marketing authorisation application on 06 August 2009.

2  Following standard checks and communication with the applicant the MHRA considered the application valid on 17 August 2009.

3  Following assessment of the application the MHRA requested further information relating to the clinical dossier on 17 September 2009 and the quality dossier on 30 December 2009 and 06 October 2010.

4  The applicant responded to the MHRA’s requests, providing further information on the clinical dossier on 27 October 2009 and the quality dossier on 21 July 2010 and 13 December 2010.

5  The application was determined on 31 March 2011.
LORATADINE 5MG/5ML ORAL SOLUTION

PL 33410/0067

STEPS TAKEN AFTER ASSESSMENT

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Loratadine 5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml of oral solution contains 1mg loratadine.

Each 1 ml of syrup also contains the following excipients:
0.0005 g sucralose (E955)
0.50 g maltitol (E965)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Oral Solution
Clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Loratadine 5mg/5ml oral solution is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

4.2 Posology and method of administration
For oral use

Adults and children over 12 years:
10ml (10mg) of the oral solution once daily. The oral solution may be taken without regard to mealtime.

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

The efficacy and safety of Loratadine oral solution in children under 2 years of age has not been established. The use is therefore not recommended in these patients.

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 30 kg. For children weighing 30kg or less, 5ml (5mg) every other day is recommended.

No dose adjustment is necessary for the elderly or patients with renal insufficiency.

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

Contains maltitol and sucralose: 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 oral solution 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 oral solution has no potentiating effects as measured by psychomotor performance studies.

Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of loratadine (see section 5.2), which may cause an increase in adverse events.

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 oral solution during pregnancy is therefore not recommended.

Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breastfeeding 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 allergic rhinitis (AR) and chronic idiopathic urticaria (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 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:

<table>
<thead>
<tr>
<th>Immune disorders</th>
<th>Anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Tachycardia, palpitation</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea, dry mouth, gastritis</td>
</tr>
<tr>
<td>Hepato-biliary disorders</td>
<td>Abnormal hepatic function</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Rash, alopecia</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Fatigue</td>
</tr>
</tbody>
</table>

4.9 Overdose

Overdosage with loratadine increased the occurrence 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: Other antihistamines for systemic use

ATC code: R06AX13.
Loratadine, the active ingredient in Loratadine 5mg/5ml oral solution, is a tricyclic antihistamine with selective, peripheral H\(_1\)-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 H\(_2\)-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\(_{\text{max}}\)) 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\(_{\text{max}}\)) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels (C\(_{\text{max}}\)) 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\(_{\text{max}}\)) 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 (E1520)  
- Sodium Benzoate (E211)  
- Disodium Edetate  
- Maltitol (Lycasin 80/55) (E965)  
- Glycerol (E422)  
- Citric Acid Monohydrate  
- Menthol  
- Flavour Peach 193421  
- Sucralose (E955)

6.2 **Incompatibilities**  
Not applicable

6.3 **Shelf life**  
3 years

Shelf life after first opening container: 3 months

6.4 **Special precautions for storage**  
No special precautions for storage.

6.5 **Nature and contents of container**  
Amber coloured transparent polyethylene terphthalate (PET) bottle with a 28mm polypropylene (PP) tamper proof child resistance cap.

&

Amber coloured round glass bottle with a 28 mm polypropylene (PP) tamper proof child resistance cap.

Pack size: 100 ml

6.6 **Special precautions for disposal**  
No special requirements.

7 **MARKETING AUTHORISATION HOLDER**  
APSLA Limited,  
Bayview House,  
49 North Strand Road,  
Dublin 3, Ireland

8 **MARKETING AUTHORISATION NUMBER(S)**  
PL 33410/0067

9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
31/03/2011

10 **DATE OF REVISION OF THE TEXT**  
31/03/2011
PACKAGE LEAFLET: INFORMATION FOR THE USER

Loratadine 5mg/5ml Oral Solution

Loratadine

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Loratadine 5 mg/5ml oral solution 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 contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Loratadine 5 mg/5 ml oral solution is and what it is used for
2. Before you take Loratadine 5 mg/5 ml oral solution
3. How to take Loratadine 5 mg/5 ml oral solution
4. Possible side effects
5. How to store Loratadine 5 mg/5 ml oral solution
6. Further information

1. WHAT LORATADINE 5MG/5ML ORAL SOLUTION IS AND WHAT IT IS USED FOR

This medicine belongs to a group of medicines called antihistamines. Throughout this leaflet, your medicine is called Loratadine oral solution.
Loratadine oral solution is used in both adults and children over 2 years of age to relieve the symptoms of hay fever such as sneezing, runny nose and burning, itchy eyes. It may also used for skin allergies such as rash, itching or urticaria (hives).

2. BEFORE YOU TAKE LORATADINE ORAL SOLUTION

Do not take Loratadine oral solution
- if you are allergic (hypersensitive) to Loratadine or any of the other ingredients of Loratadine oral solution.
- if you have had an allergic reaction to antihistamines in the past
- if you have severe liver disease

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is particularly important if you are taking
- Cimetidine (for stomach problems)
- Erythromycin (an antibiotic)
- Ketoconazole or flavonazole (for fungal infections)

Taking Loratadine oral solution with food and drink
This medicine may be taken with or without food.

Pregnancy and breastfeeding
Ask your doctor or pharmacist for advice before taking any medicine.
The safe use of loratadine during pregnancy has not been established. The use of Loratadine oral solution during pregnancy is therefore not recommended.
Loratadine, the active substance in this medicine is excreted in breast milk, therefore the use of loratadine oral solution is not recommended in breast-feeding women.

Driving and using machines
Loratadine very rarely causes drowsiness at the recommended dosage. However, individuals react differently, so if affected, do not drive or use any tools or machines.

Important information about some of the ingredients of Loratadine oral solution
This medicament product contains maltitol and sucralose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicament.
3. **HOW TO TAKE LORATADINE ORAL SOLUTION**

Loratadine oral solution is for oral use only. Shake the bottle well before use.

The usual dose is as shown in the table below:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and Children over 12 years of age</td>
<td>10ml (10mg) of the oral solution once daily</td>
</tr>
<tr>
<td>Children 2 to 12 years of age with: Body weight more than 30 kg</td>
<td>10ml (10mg) of the oral solution once daily</td>
</tr>
<tr>
<td></td>
<td>Body weight 30 kg or less</td>
</tr>
</tbody>
</table>

If you take more Loratadine oral solution than you should:
If you may have taken more Loratadine oral solution than you should, talk to a doctor or pharmacist immediately. Overdose may cause sleepiness or a faster heart beat. Immediate medical attention should be sought in the event of an overdose.

If you forget to take Loratadine oral solution:
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 a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, Loratadine oral solution can cause side effects, although not everybody gets them.

If any of the following side effects happen, stop taking Loratadine oral solution and tell your doctor immediately or go to the casualty department at your nearest hospital:
- severe allergic reaction which causes difficulty in breathing or dizziness
- hair loss
- liver problems
- fast or irregular heart beat
- fainting
- rash
- fatigue
- headache
- nausea (feeling sick)
- gastritis (an inflammation of the lining of the stomach)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE LORATADINE ORAL SOLUTION**

- Keep out of the reach and sight of children
- Do not use Loratadine oral solution after the expiry date which is stated on the carton. After EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Shelf life after first opening container is 3 months.
- Do not use Loratadine oral solution if you notice any defects or signs of deterioration. If unsure, consult your doctor or pharmacist before taking it.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **FURTHER INFORMATION**

What Loratadine oral solution contains:
- The active substance is Loratadine.
- The other ingredients are propylene glycol (E1520), sodium benzoate (E211), disodium edetate, maltitol (E965), glycerol (E422), citric acid monohydrate, menthol, flavour peach and sucrose.

What Loratadine oral solution looks like and contents of the pack:
Loratadine oral solution is a clear, colourless liquid contained in either amber coloured glass bottles with a tamper proof child resistance cap or amber coloured transparent PET bottles with a tamper proof child resistance cap.

Pack size: 100ml

**Marketing Authority Holder**
APCPharma Limited, Bayview House, 49 North Strand Road, Dublin 3, Ireland.

**Manufacturer**
APC Pharmaceuticals & Chemicals (Europe) Ltd.,
9th floor, C.P. House, 97-107 Uxbridge Road, Ealing, London W5 5TL

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