



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

Submission ID: OM-2007-3994-11

File No: OM-2007/011670

The Managing Director  
 Meditab Specialties Pty Ltd

s47G

Attention: s22

Dear Sir/Madam

— AUST R 164482

Your application for registration of **MEDITAB LORATADINE SOLUTION 1mg/mL oral liquid bottle** has been evaluated and it has been decided that the goods may be registered in the Australian Register of Therapeutic Goods (ARTG).

The approved shelf life is 3 years when stored below 30°C.

The approved containers are PET and amber glass bottles.

The approved indications are:

*For use in children 1-12 years of age for relief of the symptoms of seasonal and non-seasonal allergic rhinitis, such as sneezing, nasal discharge and itching, and ocular itching and burning, and chronic urticaria (hives).*

It is a specific condition of registration of this product that a stability testing program be initiated on the first two production batches of the goods, in accordance with the requirements of the TGA's guidelines on the stability testing of pharmaceuticals, as outlined in the TGA document *Australian Regulatory Guidelines for OTC Medicines (ARGOM)*, and that any adverse results be immediately reported to the TGA.

It is a specific condition of registration that the manufacturing process will be validated according to the requirements of the *Australian Code of Good Manufacturing Practice for Medicinal Products*, and that the manufacturer's validation report and related information will be available for review within 3 months of release for sale of the first production batch. Your assurance to this effect (email dated 6 October 2007) is noted.

Copies of the approved labels, Product Information and Consumer Medicine Information are included as Attachments 1, 2 and 3 to this letter. You are reminded that it is a condition of registration of the goods that a copy of the final printed label be provided to the TGA upon commencement of supply of the goods (condition 10 of *Standard Conditions Applying to*

Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989 refers) - please forward a copy to the OTC Medicines Section.

While the labelling of this product has been screened for compliance with Commonwealth therapeutic goods legislation, no undertaking is given that the labelling complies with the *Therapeutic Goods Advertising Code*. It is the sponsor's responsibility to ensure that all labelling meets the requirements of the Code.

A copy of the approved finished product specifications of the goods is included as Attachment 4 to this letter. All tests specified in the finished product release specifications must be performed prior to release on all batches of the product unless otherwise agreed by the TGA and indicated on the attached finished product specifications. Testing on a rotational basis or some other form of reduced testing, other than specified above, may only occur following submission of a 'variation' application and approval by the TGA.

While information in relation to validation of the method of manufacture of this product was provided in the application, no undertaking is given that method validation complies fully with the requirements of the Australian Code of GMP. Any future assessment of the manufacturer's process validation procedures by the Office of Manufacturing Quality (OMQ) of the TGA may result in further issues being raised.

The TGA eBusiness Services website contains a printable Certificate of Registration for this good. The registration of the goods commences on the day specified for the purpose in the Certificate of Registration. The goods may not be supplied before this date.



Yours faithfully

s22  


Delegate of the Secretary  
OTC Medicines Section  
Office of Non-Prescription Medicines  
20 August 2009

attachment

ATTACHMENT ..... 1 ..... PAGE 1  
 OF 4  
 Date 20/9/09  
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<p>Contains preservative sodium benzoate          Does not contain sugar or gluten. Contains          maltitol (50%). May have a laxative effect or          cause diarrhoea.</p>	<p>20 mg/5ml  <b>Meditab<sup>®</sup>          Loratadine</b>          20 mg/5ml          Contains Loratadine 5mg/5ml          RAPID RELIEF FROM SYMPTOMS OF          HAYFEVER &amp; ALLERGIC RHINITIS          OR HIVES.          → NON-DROWSY ANTIHISTAMINE          → SWEET &amp; PEACH FLAVOURED          → FOR CHILDREN 1-12 YEARS</p>  <p>100mL</p>	<p><b>RECOMMENDED DOSAGE</b>          Not recommended for children under 1 year of age. Consult          your doctor or pharmacist before giving to children aged          1-2 years.  <b>Children 1-2 years: 2.5 mL once daily</b>  <b>Children 2-12 years:</b>  <b>Up to 30 kg: 5 mL once daily</b>  <b>Over 30 kg: 10 mL once daily</b>          If condition persists, consult your doctor or pharmacist</p>
<p>STORE BELOW 30°C WITH CHILD RESISTANT CAP.</p>	<p> Gipha Genpharm Australia Pty Ltd.          15/10 Buttrick Road, Ormeau QLD 4208, Australia.</p>	<p>Code No.:</p>

Size: 125 x 55mm

Date: 27-12-08

change to:  
 Meditab Specialities Plc  
 Suite 4, 3460 Pacific Hwy  
 Springwood QLD 4127

Rapid 24-hour Relief  
HAYFEVER & ALLERGY RELIEF  
NON-DROWSY ANTIHISTAMINE  
FOR CHILDREN 1-12 YEARS

# Meditab® Loratadine Solution

PHARMACY MEDICINE  
KEEP OUT OF REACH OF CHILDREN

## Meditab® Loratadine Solution

Contains Loratadine 5mg/5ml

RAPID RELIEF FROM SYMPTOMS OF  
HAYFEVER & ALLERGIC RHINITIS  
OR HIVES.

- NON-DROWSY ANTIHISTAMINE
- SWEET & PEACH FLAVOURED
- FOR CHILDREN 1-12 YEARS



AUST R XXXXX

100mL

## Meditab® Loratadine Solution

Rapid 24-hour Relief  
HAYFEVER & ALLERGY RELIEF  
NON-DROWSY ANTIHISTAMINE  
FOR CHILDREN 1-12 YEARS

### CONSUMER INFORMATION

LORATADINE SOLUTION provides rapid 24-hour relief from the symptoms of hay fever, seasonal & non-seasonal allergic rhinitis or hives, without causing drowsiness. Just one daily dose relieves

- Sneezing
- Watery eyes, Itchy eyes
- Runny nose
- Itchy skin rash/hives

### RECOMMENDED DOSAGE

Not recommended for children under 1 year of age. Consult your doctor or pharmacist before giving to children aged 1-2 years.  
Children 1-2 years: 2.5 mL once daily  
Children 2-12 years:  
Up to 30 kg: 5 mL once daily  
Over 30 kg: 10 mL once daily  
If condition persists, consult your doctor or pharmacist.

STORE BELOW 30°C

PHARMACY MEDICINE  
KEEP OUT OF REACH OF CHILDREN

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RAPID RELIEF FROM SYMPTOMS OF  
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OR HIVES.

- NON-DROWSY ANTIHISTAMINE
- SWEET & PEACH FLAVOURED
- FOR CHILDREN 1-12 YEARS



AUST R XXXXX

100mL

## Meditab® Loratadine Solution

Rapid 24-hour Relief  
HAYFEVER & ALLERGY RELIEF  
NON-DROWSY ANTIHISTAMINE  
FOR CHILDREN 1-12 YEARS

The bottle has child resistant and tamper-proof cap. Do not use if the cap appears damaged or broken. Engage the child resistant cap for storage after use.

Contains preservative sodium benzoate. Does not contain sugar or gluten. Contains maltitol (50%). May have a laxative effect or cause diarrhoea.

BARCODE

Cipla Genpharm Australia Pty Ltd.  
15/10 Burnside Road, Ormeau QLD 4208, Australia

Manufactured at Australian GMP approved facility in India


Size: 125x 50 x50 mm

Date: 27-12-08

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 SUB ID: 0M-200 7-3994-11

Code No., BN & EXP will be inkjet printed at the time of packing.

Change to  
Meditab Specialities P/L  
Suite 4, 3460 Pacific  
Hwy. Springwood  
QLD 4127

<p>Contains preservative sodium benzoate Does not contain sugar or gluten. Contains naltrexol (50%). May have a laxative effect or cause diarrhoea.</p> <p>STORE BELOW 30°C WITH CHILD RESISTANT CAP.</p> <p> Cipla Genpharm Australia Pty Ltd. 15/10 Burnside Road, Ormeau QLD 4208, Australia.</p> <p>PARF 19 2008</p>	<p>PHARMACY MEDICINE KEEP OUT OF REACH OF CHILDREN</p> <p><b>Meditab<sup>®</sup></b> <b>Loratadine</b> Solution</p> <p>Contains Loratadine 5mg/5ml</p> <p>RAPID RELIEF FROM SYMPTOMS OF HAYFEVER &amp; ALLERGIC RHINITIS OR HIVES.</p> <p>→ NON-DROWSY ANTIHISTAMINE → SWEET &amp; PEACH FLAVOURED → FOR CHILDREN 1-12 YEARS</p> <p>24-Hour Relief</p> <p>200mL</p>	<p><b>RECOMMENDED DOSAGE</b></p> <p>Not recommended for children under 1 year of age. Consult your doctor or pharmacist before giving to children aged 1-2 years.</p> <p>Children 1-2 years: 2.5 mL once daily Children 2-12 years: Up to 30 kg: 5 mL once daily Over 30 kg: 10 mL once daily</p> <p>Code No:</p>
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Size: 135 x 70mm

change to

Date: 27-12-08

Meditab Specialities P/L  
Suite 4, 3460 Pacific Hwy.  
Springwood QLD 4127.

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Rapid 24-hour Relief  
HAYFEVER & ALLERGY RELIEF  
NON-DROWSY ANTIHISTAMINE  
FOR CHILDREN 1-12 YEARS

# Meditab<sup>®</sup> Loratadine Solution

XXXXX

PHARMACY MEDICINE  
KEEP OUT OF REACH OF CHILDREN

# Meditab<sup>®</sup> Loratadine Solution

Contains Loratadine 5mg/5ml

RAPID RELIEF FROM SYMPTOMS OF  
HAYFEVER & ALLERGIC RHINITIS  
OR HIVES

- NON-DROWSY ANTIHISTAMINE
- SWEET & PEACH FLAVOURED
- FOR CHILDREN 1-12 YEARS



200mL

AUST R XXXXX

# Meditab<sup>®</sup> Loratadine Solution

Rapid 24-hour Relief  
HAYFEVER & ALLERGY RELIEF  
NON-DROWSY ANTIHISTAMINE  
FOR CHILDREN 1-12 YEARS

### CONSUMER INFORMATION

LORATADINE<sup>®</sup>SOLUTION provides rapid 24-hour relief from the symptoms of hay fever, seasonal & non-seasonal allergic rhinitis or hives, without causing drowsiness. Just one daily dose relieves

- Sneezing
- Watery eyes, Itchy eyes
- Runny nose
- Itchy skin rashes/ives

### RECOMMENDED DOSAGE

Not recommended for children under 1 year of age. Consult your doctor or pharmacist before giving to children aged 1-2 years.  
Children 1-2 years: 2.5 mL once daily  
Children 2-12 years:  
Up to 30 kg: 5 mL once daily  
Over 30 kg: 10 mL once daily  
If condition persists, consult your doctor or pharmacist.

STORE BELOW 30°C

PHARMACY MEDICINE  
KEEP OUT OF REACH OF CHILDREN

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Contains Loratadine 5mg/5ml

RAPID RELIEF FROM SYMPTOMS OF  
HAYFEVER & ALLERGIC RHINITIS  
OR HIVES

- NON-DROWSY ANTIHISTAMINE
- SWEET & PEACH FLAVOURED
- FOR CHILDREN 1-12 YEARS



200mL

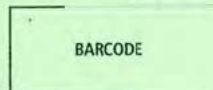
AUST R XXXXX

# Meditab<sup>®</sup> Loratadine Solution

Rapid 24-hour Relief  
HAYFEVER & ALLERGY RELIEF  
NON-DROWSY ANTIHISTAMINE  
FOR CHILDREN 1-12 YEARS

The bottle has child resistant and tamper-proof cap. Do not use if the cap appears damaged or broken. Engage the child resistant cap for storage after use.

Contains preservative sodium benzoate. Does not contain sugar or gluten. Contains maltitol (50%). May have a laxative effect or cause diarrhoea.



Cipla Pharmaceuticals Pty Ltd.  
15/10 Riverside Road, Ormeau QLD 4208, Australia

Manufactured at Australian GMP approved facility in India

Size: 155 x 60 x 60mm

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Code No., BN & EXP will be inkjet printed at the time of packing.

change to:  
Meditab Specialties  
Suite 4, 3460 Pacific  
Hwy, Springwood  
QLD 4127

## MEDITAB LORATADINE SOLUTION PRODUCT INFORMATION

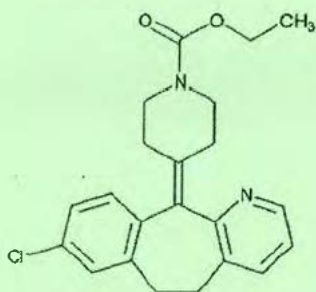
### COMPOSITION

Active. Loratadine.

Excipients: Propylene glycol, Disodium Edetate, Maltitol (Lycasin 80/55), Glycerol, Citric acid Monohydrate, Menthol, artificial flavouring - Flavour Peach 9/A07169, Sucralose and purified water with sodium benzoate as preservative.

### DESCRIPTION

Chemical name: ethyl 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]-cyclohepta[1,2-b]pyridin-11-ylidene)-1-piperidinecarboxylate. Molecular formula:  $C_{22}H_{23}N_2ClO_2$ . MW: 382.9



It appears as a white to off white crystalline powder that is freely soluble in methanol, ethanol and chloroform, soluble in ether and practically insoluble in water.

### ACTIONS

#### Pharmacology.

Loratadine is a potent, long acting antihistamine with relative selectivity for peripheral H<sub>1</sub>-receptors. Loratadine does not readily penetrate into the CNS. It exhibits greater affinity for peripheral H<sub>1</sub>-receptors than for central H<sub>1</sub>-receptors. These properties account for the observed lack of sedation. The incidence of sedation with loratadine is comparable to that of placebo.

Loratadine has a rapid onset of action after oral administration, usually within one hour.

Specific studies involving sleep tests with EEG tracings, motor car driving under actual driving conditions, as well as psychomotor performance tests, have not shown any significant difference between Loratadine 10 mg and placebo with respect to interaction with the central nervous system or impairment of performance.

Specific clinical pharmacology studies were conducted with concomitant administration of loratadine with therapeutic doses of erythromycin, ketoconazole and cimetidine for ten days in healthy subjects. Although increased plasma concentrations

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(AUC 0 to 24 hours) of loratadine and/or its active metabolite desloratadine were observed, there were no clinically relevant changes in the safety profile of loratadine as assessed by electrocardiographic parameters including QTc interval, clinical laboratory tests, vital signs and adverse events.

Additionally, cardiac repolarisation was not altered, nor were other electrocardiographic parameters (see Interactions).

#### **Pharmacokinetics.**

Loratadine is well absorbed with peak plasma levels occurring at approximately one or two hours after dosing. The drug is almost totally metabolised. It has an active metabolite (desloratadine); this metabolite corresponds to 1 to 2% of the dose.

In humans, loratadine is extensively bound to plasma protein (97 to 99%), and desloratadine is moderately bound (73 to 76%).

Approximately 40% of the dose is excreted in the urine and 42% in the faeces in a ten day period. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. The mean elimination half-life of loratadine in normal volunteers is approximately 12 hours, while that of desloratadine is approximately 20 hours. Renal impairment has no significant effect on loratadine clearance. In children, clearance appears to be marginally faster. Concomitant ingestion of food and loratadine may delay absorption (by approximately one hour) and may increase the AUC (area under the curve) for both loratadine (40%) and its active metabolite desloratadine (approximately 15%). These differences would not be expected to be clinically important.

#### **INDICATIONS**

Solution. Use in children 1 to 12 years. Relief of symptoms associated with allergic rhinitis such as sneezing, nasal discharge and itching, and ocular itching and burning.

Relief of symptoms and signs of chronic allergic skin disease (see Precautions, Use in children).

#### **CONTRAINDICATIONS**

Hypersensitivity or idiosyncrasy to loratadine or hypersensitivity to any excipients (see composition).

#### **PRECAUTIONS**

##### **Immune system.**

In a 17 month study in monkeys, loratadine demonstrated no functional impairment of the immune system, as indicated by mortality, peripheral leucocyte count or incidences of inflammatory reactions, autoimmune disease and malignancy. Specific studies investigating the effect of loratadine on immune function in humans have not been performed.

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***Impaired hepatic function.***

As with all drugs metabolised by the liver, loratadine should be used with caution in patients with severe liver dysfunction.

***Carcinogenesis, mutagenesis, impairment of fertility.******Carcinogenesis***

Loratadine administered in the diet to mice for 18 months at doses greater than 12 mg/kg/day resulted in an increased incidence of benign hepatic tumours. A two year study in rats showed no increase in the incidence of carcinogenicity in loratadine treated animals compared with control animals at dietary doses up to 25 mg/kg/day. Fertility. Animal studies showed that loratadine had an adverse effect on male fertility when administered to rats at doses greater than 24 mg/kg/day. The clinical relevance of this observation is unknown at this time.

***Use in pregnancy. (Category B1)***

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage.

The safe use of loratadine during pregnancy has not been established. Therefore the compound should be used only if the potential benefit justifies the potential risk to the fetus.

Reproductive studies in pregnant rats and rabbits showed no evidence of embryotoxic or teratogenic activity at loratadine doses up to 96 mg/kg/day. In pregnant rats, loratadine and its metabolite crossed the placental barrier, distributing in fetal tissues in a pattern similar to that in maternal tissues but at lower concentrations.

***Use in lactation.***

The safe use of loratadine during lactation has not been established. Therefore the compound should be used only if the potential benefit justifies the potential risk to the infant.

A study in lactating women showed that breast milk levels of loratadine and its active metabolite parallel their respective plasma concentrations after oral administration. Acute toxicity studies have demonstrated that neonatal rats and mice are more sensitive to loratadine than the adults of the corresponding species. The use of loratadine by breastfeeding mothers is not recommended.

***Use in children.***

Loratadine Solution has been shown to be effective and safe for the control of symptoms of allergic rhinitis and allergic skin disorders in children 2 years of age and older.

Efficacy studies have not yet been conducted using loratadine in children younger than 2 years of age. However, the range of concentrations found in children 1 to 2 years of age after the administration of a single 2.5 mg dose of loratadine (from Meditab Loratadine Solution) are within the ranges of concentrations for older children.

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**Interactions**

Various tests (psychomotor tests, wakefulness tests, cognitive function and mood tests and driving tests) have shown that Meditab Loratadine does not interact with alcohol. When administered concomitantly with diazepam, Meditab Loratadine has no potentiating effects as measured by psychomotor performance studies.

Loratadine (10 mg once daily) has been safely coadministered with therapeutic doses of erythromycin, cimetidine and ketoconazole in controlled clinical pharmacology studies. Although increased plasma concentrations (AUC 0 to 24 hours) of loratadine and/or desloratadine were observed following coadministration of loratadine with each of these drugs in normal volunteers, there were no clinically relevant changes in the safety profile of loratadine and no reports of sedation or syncope (see Actions, Pharmacology).

**Laboratory tests.**

Meditab Loratadine should be discontinued approximately 48 hours prior to skin testing procedures, since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

**ADVERSE REACTIONS**

In worldwide controlled clinical studies, the incidence of adverse effects associated with Loratadine tablets and Solution has been comparable to that of placebo. In these trials, loratadine has shown no clinically significant sedative or anticholinergic properties.

Adverse experiences reported in children taking Loratadine Solution 10 mg once daily consisted of nervousness (4% versus placebo 1%), hyperkinesia (3% versus placebo 0.6%), sedation (5% versus placebo 5%) and headache (3% versus placebo 8%).

Adverse experiences occurring in less than 1% of patients are listed below.

Cardiovascular. Hypertension, hypotension, syncope, palpitations, tachycardia, chest pain, epistaxis.

Gastrointestinal. Dyspepsia, diarrhoea, constipation, abdominal/ gastric pain, nausea.

Renal. Increased frequency of urination, urine discolouration.

Respiratory. Nasal dryness, pharyngitis, coughing.

Other. Depression, dizziness, fever, nervousness, viral infection, insomnia, menstruation delay, myalgia, pruritus, altered taste, paroniria, tinnitus, rash on face, increased saliva, increased appetite, paraesthesia, malaise and alopecia.

The incidence and general nature of these rarer reports were similar in both placebo treated and Loratadine treated patients.

During the marketing of loratadine, alopecia, anaphylaxis and abnormal hepatic function have been reported rarely.

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**DOSAGE AND ADMINISTRATION*****Children 2 to 12 years.***

Bodyweight > 30 kg. 10 mL Meditab Loratadine Solution once daily.

Bodyweight less than or equal to 30 kg. 5 mL Meditab Loratadine Solution once daily.

***Children 1 to 2 years.***

2.5 mL Meditab Loratadine Solution once daily.

It is not known if equivalent doses of Meditab Loratadine Solution and tablets are bioequivalent. This should be considered when changing the dosage form. However, similar plasma levels of loratadine and its active metabolite (desloratadine) to those previously reported in adults are seen in children.

***Impaired hepatic function.***

For patients with severe hepatic impairment, a lower initial dose (5 mg daily) is recommended.

***Overdosage******Symptoms.***

Somnolence, tachycardia and headache have been reported with overdoses. In volunteer studies, single doses of up to 160 mg have been administered without any untoward effects.

***Treatment.***

In the event of overdosage, consideration should be given to adsorption of any unabsorbed loratadine by use of activated charcoal. Otherwise, treatment, which should be started immediately, is symptomatic and supportive. Loratadine is not eliminated by haemodialysis; it is not known if loratadine is eliminated by peritoneal dialysis. After emergency treatment, the patient should continue to be medically monitored. Contact the Poisons Information Centre 131126 for information on the management of overdosage.

**PRESENTATION**

Solution: 1 mg/mL (clear, peach flavoured): 100 mL, 200 mL.

**STORAGE**

Solution: Store below 30 deg. C.

**POISON SCHEDULE**

S2.

**SPONSOR**

MEDITAB SPECIALITIES Pty Ltd  
Suite 4, "The Groves", 3990 Pacific Highway,  
LOGANHOLME QLD 4129  
TGA Approval Date: TBD

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# MEDITAB LORATADINE SOLUTION

## CONSUMER MEDICINE INFORMATION

### *Loratadine*

#### **What is in this leaflet?**

This leaflet answers some common questions about Meditab Loratadine.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine. You may need to read it again.**

#### **What Meditab Loratadine is used for**

Meditab Loratadine relieves symptoms associated with allergic rhinitis (hayfever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

Meditab Loratadine may also be used to relieve symptoms associated with a skin condition called chronic urticaria (also called hives); these symptoms include itching, redness and lumps on the skin.

Meditab Loratadine can be used in adults and children aged 1-12 years.

Meditab Loratadine belongs to a class of medicines known as antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances which the body is allergic to.

Your doctor or pharmacist, however, may prescribe Meditab Loratadine for another purpose.

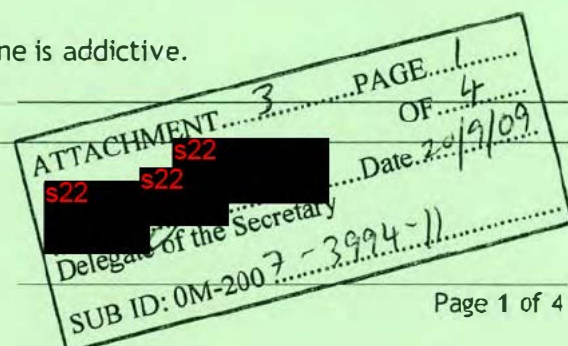
**Ask your doctor or pharmacist if you have any questions about why Meditab Loratadine has been prescribed for you.**

There is no evidence that Meditab Loratadine is addictive.

#### **Before you take Meditab Loratadine**

#### **When you must not take it**

19th August 2009



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**Do not take Meditab Loratadine if:**

- you have an allergy to Meditab Loratadine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, difficulty in breathing or faintness.

**Do not take Meditab Loratadine if you are pregnant or breastfeeding unless you and your doctor or pharmacist have discussed the risks and benefits involved.**

**Do not give Meditab Loratadine to children less than 1 year old.**

**Do not take Meditab Loratadine after the expiry date printed on the pack.**

**Do not take Meditab Loratadine if the packaging is torn or shows signs of tampering.**

***Before you start to take it*****You must tell your doctor or pharmacist:**

if you are allergic to any other medicines or any foods, dyes or preservatives  
if you have liver disease or any other medical conditions.

***Taking other medicines***

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

**How to take Meditab Loratadine*****How much to take*****Children 2-12 years of age:**

Over 30kg - 10mL of Meditab Loratadine Solution once daily

Less than 30kg - 5mL of Meditab Loratadine Solution once daily.

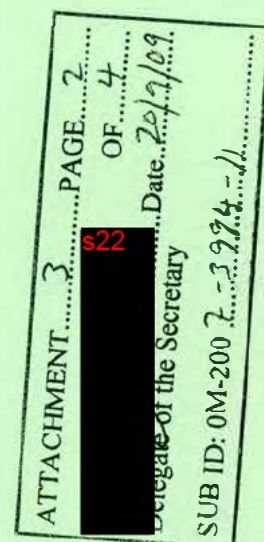
**Children 1-2 years of age.:**

Consult your doctor or pharmacist before use  
2.5mL of Meditab Loratadine Solution once daily.

It does not matter if you take Meditab Loratadine before or after food.

***How to take it***

Solution: Take it with a glass of water.



**If you take too much (overdose)**

Immediately telephone your doctor, pharmacist or Poisons Information Centre (13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Meditab Loratadine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

**While you are taking Meditab Loratadine*****Things you must do***

Tell all doctors, dentists and pharmacists who are treating you that you are taking Meditab Loratadine.

Tell your doctor or pharmacist if you become pregnant while you are taking Meditab Loratadine.

***Things you must not do***

Do not give Meditab Loratadine to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor or pharmacist says to.

***Things to be careful of***

Make sure you know how you react to Meditab Loratadine before you drive a car or operate machinery. Meditab Loratadine is unlikely to make you drowsy. If you are drowsy, do not drive a car or work with machinery.

Stop taking Meditab Loratadine 48 hours before you have any skin tests. Antihistamines may interfere with the results of skin tests.

**Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Meditab Loratadine. Meditab Loratadine helps most children with allergies, but it may have unwanted effects in a few people.

Like other medicines, Meditab Loratadine can cause some side effects. If they occur, they are most likely to be minor and temporary.

However, some may be serious and need medical attention.

Ask your doctor or pharmacist any questions you may have. The most commonly reported unwanted events were:

ATTACHMENT..... <sup>3</sup> .....	PAGE..... <sup>3</sup> .....
s22	OF..... <sup>4</sup> .....
Delegate of the Secretary	..Date. 20/7/09
SUB ID: 0M-2007-3994-11	

## Meditab Loratadine Solution

## Consumer Medicine Information

nervousness  
fidgeting  
sleepiness  
headache  
upset stomach

Rare instances of hair loss was also reported. Other unwanted effects may occur in some people taking Meditab Loratadine.

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**After taking Meditab Loratadine**


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**Storage**

Keep your Solution in the bottle until it is time to take it.

Keep your Solution in a cool dry place where the temperature stays below 30 degree C.

Do not leave it in the car on hot days or on window sills. Keep it where children cannot reach it.

**Disposal**

If your doctor or pharmacist tells you to stop taking Meditab Loratadine or the medicine has passed the expiry date, ask your pharmacist what to do with any that are left over.

**Product description**

Meditab Loratadine Solution can be bought without a doctor's prescription.

**What it looks like**

Meditab Loratadine Solution is a clear solution.

**Ingredients**

Meditab Loratadine Solution contains:

Active: Loratadine 5mg/5mL

Excipients: Propylene glycol, Disodium Edetate, Maltitol solution, Glycerol, Citric acid Monohydrate, Menthol, artificial flavouring - Flavour Peach, Sucralose and purified water with sodium benzoate as preservative.

It does not contain lactose or gluten.

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**Sponsor**


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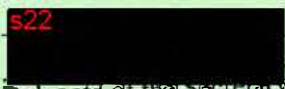
MEDITAB SPECIALITIES Pty Ltd  
Suite 4, "The Groves", 3990 Pacific Highway, LOGANHOLME QLD 4129

**Australian Registration Numbers:**

Solution: 100mL and 200mL AUST R TBC

Date of Preparation: August 2009.

19th August 2009

ATTACHMENT.....3.....	PAGE.....4.....
	OF.....4.....
Delegate of the Secretary	Date 20/9/09
SUB ID: OM-200	7-3994-11

Page 4 of 4

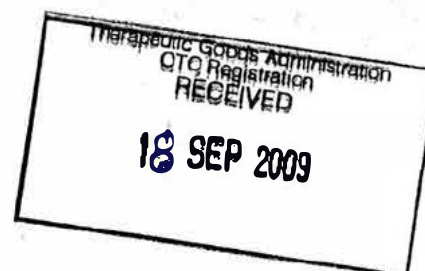
LORATADINE ORAL SOLUTION USP		
3.2. P.5 Control of Drug Product		
Document 3.2. P.5.1 Specification(s)		
TEST	Release Specification	Expiry Specification
Description	Clear, colourless liquid, packed in 100 ml amber coloured glass / PET bottle with 28 MM PP temper proof child resistance cap.	Clear, colourless liquid, packed in 100 ml amber coloured glass / PET bottle with 28 MM PP temper proof child resistance cap.
Weight per ml (g)	NLT 1.150 NMT 1.250	NLT 1.150 NMT 1.250
pH	NLT 2.50 NMT 3.10.	NLT 2.50 NMT 3.10.
Clarity	Solution should be clear.	Solution should be clear.
Identification A (By TLC)	The Rf value of the principal spot obtained from the sample solution corresponds to that obtained from the standard solution.	The Rf value of the principal spot obtained from the sample solution corresponds to that obtained from the standard solution.
B (By HPLC)	The retention time of Loratadine peak obtained in the chromatogram of sample solution corresponds to that of the standard solution as obtained in the test of assay.	The retention time of Loratadine peak obtained in the chromatogram of sample solution corresponds to that of the standard solution as obtained in the test of assay.
Microbial Limits	Total aerobic microbial count: NMT 100 cfu/ml Yeast and mould: NMT 50 cfu/ml <u>As per USP Standards:</u> Escherichia coli: Should be absent / 10ml Salmonella: Should be absent / 10ml. <u>As per In-House Standards:</u> Pseudomonas aeruginosa: Should be absent / 10ml. Staphylococcus aureus: Should be absent / 10ml Enterobacteria and certain other gram negative bacteria: Not more than 100/ ml	Total aerobic microbial count: NMT 100 cfu/ml Yeast and mould: NMT 50 cfu/ml <u>As per USP Standards:</u> Escherichia coli: Should be absent / 10ml Salmonella: Should be absent / 10ml. <u>As per In-House Standards:</u> Pseudomonas aeruginosa: Should be absent / 10ml. Staphylococcus aureus: Should be absent / 10ml Enterobacteria and certain other gram negative bacteria: Not more than 100/ ml
Deliverable Volume	The average volume of solution obtained from the 10 containers is not less than 100 % (100ml) & volume of no container is less than 95% (95ml) of the volume declared in the labelling. Average(ml):NLT 100 Range (ml):NLT 100	The average volume of solution obtained from the 10 containers is not less than 100 % (100ml) & volume of no container is less than 95% (95ml) of the volume declared in the labelling. Average(ml):NLT 100 Range (ml):NLT 100
Related Compounds	Impurity I NMT 0.30 % Impurity II NMT 0.30 % Any other individual impurity NMT 0.20 % Total impurities NMT 0.50 %	Impurity I NMT 0.30 % Impurity II NMT 0.30 % Any other individual impurity NMT 0.20 % Total impurities NMT 0.50 %
Assay Content of Loratadine (mg/5ml)	NLT 4.700 NMT 5.250	NLT 4.700 NMT 5.250
Preservative Content Sodium Benzoate (% w/v)	NLT 0.090 NMT 0.110	NLT 0.090 NMT 0.110

ATTACHMENT.....4.....PAGE.....1.....  
 s22 OF.....1.....  
 Date 20/9/07  
 Delegate of the Secretary  
 SUB ID: OM-200 7-3994-11



15 September 2009

Office of OTC Medicines  
Therapeutic Goods Administration  
PO Box 100  
Woden, ACT 2606



Re: Notification – Meditab Loratadine Solution 1mg/mL (AUST R 164482)  
Application ID: OM-2009-GL-10529-3

OM-09-00979-3

Dear Sir or Madam,

A notification has been submitted to the TGA for the above mentioned product.

The following changes have been made to the above mentioned product:

1. PSC – Recommended storage conditions more restrictive – storage conditions reduced from 'Store below 30°C' to 'Store below 25°C'. Refer copies of original stability data supporting the product registration along with copies of assurance letters from original submission provided as Attachment 1.

**Assurance**

No aspects of the labelling, PI, CMI, pharmaceutical data, manufacturing processor other details have been changed or are to be changed, other than the changes nominated in this application and those made in conformity with the 'Changes table'.

2. MOS – Overseas manufacturer (includes site of manufacture), if GMP clearance certificate is provided – Include the following manufacturing site:

Cipla Limited  
Plot No. S-103 S-104 and L139 to L146  
Verna Industrial Area Verna Salcette Goa  
INDIA  
Manufacturer ID: 18858  
Manufacturing steps : Manufacture of dosage form, Packaging and labelling, Release for supply, Testing chemical and physical , Testing microbial

Refer copy of current GMP Preclearance certificate for site provided as Attachment 4.

**Assurances**

No aspects of the labelling, PI, CMI, pharmaceutical data, manufacturing processor other details have been changed or are to be changed, other than the changes nominated in this application and those made in conformity with the 'Changes table'.

GMP Preclearance certificate has been supplied.

3. MUP – Update of current overseas manufacturer pre-clearance details – Current manufacturer Mediorals Laboratories Pvt Ltd pre-clearance details updated. Refer current GMP Preclearance certificate MI-17112004-CL-000578-1 provided as Attachment 5.

**Assurance**

The only change made is an update of the GMP preclearance number of the current manufacturer that manufactures this good.

4. Removal of 200mL pack size from ARTG record.

The following attachments were included in support of this application:


1. Copy of the validated application
2. Completed fee payment form\*
3. Copy of Stability data from original submission supporting change in storage condition reduction
4. Copy of GMP Preclearance certificate for Cipla Ltd – Goa Site (MI-29062007-CL-008437-11)
5. Copy of GMP Preclearance certificate for Mediorals Laboratories Pvt Ltd (MI-17112004-CL-000578-1)

\* Payment of \$1230.00 will be made directly by the sponsor Meditab Specialities Pty Ltd.

Please do not hesitate to contact me if you require any further information for this notification.

Yours faithfully,

s22



s47G

Ph: s22

Fax: s22

Mob: s22



The Managing Director  
s47G

**ATTENTION:** s22

**File No:** 2012/023267

**Submission Nos:** OM-2012-01666-1, OM-2012-01667-1, OM-2012-01668-1,  
OM-2012-01671-1, OM-2012-01672-1, OM-2012-01673-1 & OM-2012-01674-1

Dear Sir/Madam

I refer to your application dated 26 November 2012 on behalf of Cipla-Oz Pty Ltd to vary the registration details in the Australian Register of Therapeutic Goods (the 'ARTG') under the provisions of the *Therapeutic Goods Act 1989* ("the Act") of the medicines listed in the Appendix to this letter.

The proposed variation to the ARTG entry entails changing the specifications for Purified Water, used as a raw material in the medicines, to be consistent with the monograph for Purified Water in the current edition of the British Pharmacopoeia.

The TGA has completed a review of your application (Submission Nos: OM-2012-01666-1, OM-2012-01667-1, OM-2012-01668-1, OM-2012-01671-1, OM-2012-01672-1, OM-2012-01673-1 & OM-2012-01674-1) and pursuant to Subsection 9D(3) of the Act, I am notifying you of my decision to **approve the proposed variation to registration** of this good.

The basis for approving this variation entailed a review of the information and data provided with the original letter of application (including your assurances that no other changes have been made), together with any subsequent correspondence and submissions relating to the application.

### **Appeal Provisions**

This decision is an "initial decision" within the meaning of Section 60 of the Act. This means that if your interests are affected by the decision, you may seek review of the decision by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister for Health and Ageing  
Parliament House  
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker (the signatory of this letter) to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the *Administrative Appeals Tribunal Act 1975*, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours faithfully

s22

DELEGATE OF THE SECRETARY  
Application Management & Export Section  
Office of Medicines Authorisation

12 February 2013

RECEIVED

21 SEP 2010

20 September 2010

The Director  
Office of Non-Prescription Medicines  
Therapeutic Goods Administration  
PO BOX 100  
WODEN ACT 2606

**OM-2010-01179-3 Change to Multiple Submissions****MEDITAB LORATADINE SOLUTION 1mg/mL oral liquid bottle AUST R 164482**

Dear Sir,

A notification has been submitted to the TGA for the above mentioned registrations.

The change is as follows:

**FINISHED PRODUCT**

The following changes were made as part of the parent application and identical changes have been made to the above mentioned registrations:

**KSP - Introduction of a measuring device**

A measuring cup will be included with the above mentioned products. Details including dimension, diagram and assurance from the measuring cup manufacturer are included as Attachment 2 to support this notification.

**Assurance:**

No Aspects of the labelling, PI, CMI pharmaceutical data, manufacturing process or other product details have been changed or are to be changed, other than the changes nominated in this application and those made in conformity with the 'Changes table'

The following additional information is included in support of these applications:

1. Copy of the validated application form

\* Payment of \$1260.00 will be made separately by Meditab and will reference invoice number ONL049465 as no Invoice was issued by the eBS system.

Please feel free to contact me if you require any further information in relation to this notification.

Yours faithfully,

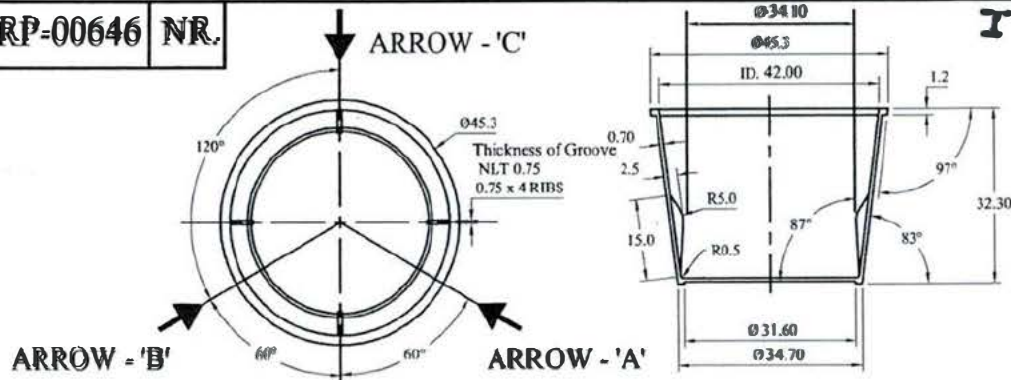
s22  
[Redacted signature block]

Ph: s22  
Fax: s22  
Email: s22 s47G  
[Redacted contact information]

RP-00646 NR.

ITEM CODE:- 506UB

PERMISSIBLE TOL ON DIM'S  
WHEN NOT SPECIFIED  
LINEAR  $\pm 0.25$ , ANGULAR  $\pm 0^{\circ}.30'$

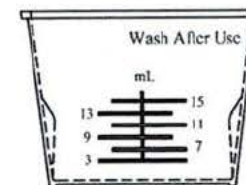


PLAN VIEW

SECTION - 'X' - 'X'



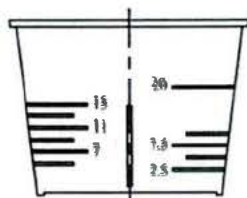
VIEW FROM ARROW - 'A'



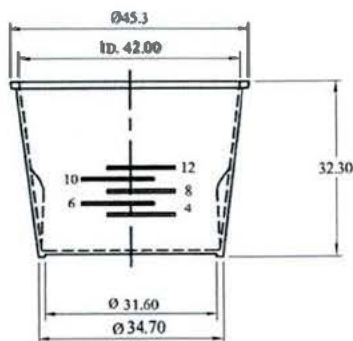
VIEW FROM ARROW - 'B'

ARROW - 'B'

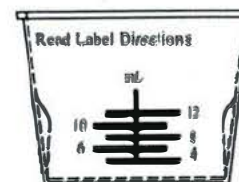
ARROW - 'A'



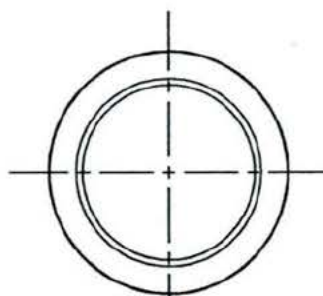
ELEVATION



SIDE VIEW



VIEW FROM ARROW - 'C'



BOTTOM VIEW

NOTES:

- 1.) ALL MARKING LINES & TEXT ENGRAVED FROM OUTSIDE AS SHOWN.
- 2.) ALL TEXT HEIGHT SHOULD BE 3.0mm
- 3.) STOCK - 0.70/0.75mm

APPROVED DRAWING  
CIPLA  
PACKAGING DEVELOPMENT DEPT.

NO DATE REVISION DRN CHD APP

CAD DRG. DO NOT SCALE		ALL DIMENSIONS ARE IN MM.	
MATERIAL: P.P. (SRM 100NC)		PROCESS: -----	
DRN: S22	29/01/2009	<b>RAJESH PLASTICS</b>	
CHD:			
NAME		DATE	
WT. -: 4.0 +/- 0.25gm		Unit: 15, Extension-2, Agarwal Udyog Nagar, Satwadi Road, Village-Wadi, Vasni-East, DIST. THANE - 401 208 email: info@rajeshplastics.com	
TITLE: (Item Code: 506UB) <b>MEASURING CUP</b> [2.5mL TO 20mL]		DRG. NO. <b>RP-00646</b>	REV. NR.