### **Consumer Medicine Information**

### What is in this leaflet:

This leaflet answers some common questions about CHILDREN'S CLARATYNE.

It does not contain all the available information.

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 CHILDREN'S CLARATYNE is used for

CHILDREN'S CLARATYNE contains an active ingredient called loratadine, which 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.

CHILDREN'S CLARATYNE tablets are used to relieve the symptoms of hayfever (seasonal allergic rhinitis) such as sneezing, runny or itchy nose, and burning, watery or itchy eyes.

Hayfever is usually caused by allergy to various types of allergens including moulds and pollens of trees, grasses or weeds.

Your doctor or pharmacist, however, may prescribe CHILDREN'S CLARATYNE for another purpose.

Ask your doctor or pharmacist if you have any questions about why CHILDREN'S CLARATYNE has been prescribed for you.

There is no evidence that CHILDREN'S CLARATYNE is addictive.

## Before you take CHILDREN'S CLARATYNE

When you must not take it

Do not take CHILDREN'S CLARATYNE if you are pregnant or breast feeding unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not take CHILDREN'S CLARATYNE if you have an allergy to CHILDREN'S CLARATYNE 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 give CHILDREN'S CLARATYNE tablets to children under 6 years of age. CHILDREN'S CLARATYNE syrup is available from your pharmacy for use in young children.

Do not use this product when experiencing first time hayfever symptoms without advice from a healthcare professional.

Do not take CHILDREN'S CLARATYNE if the packaging is torn or shows signs of tampering.

Consult your doctor or pharmacist if you are not sure whether you should start taking CHILDREN'S CLARATYNE.

Before you start to take it

Consult 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.

If you have any of the following symptoms.

- · ear pain or discomfort
- pain in your face
- loss of smell
- · taste disturbances or loss of taste
- feve
- · chest discomfort, cough
- blocked nose without any other symptoms
- · symptoms on only one side of your nose
- thick, green or yellow discharge from your nose
- · repeated nosebleed
- a drip down the back of your throat with thick mucus and/or runny nose

These symptoms are not usually found in hayfever.

Taking other medicines

Consult 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.

Your doctor and pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

## How to take CHILDREN'S CLARATYNE

How much to take

Children 6-9 years: ONE tablet once daily as necessary.

Adults and Children 9 years+: TWO tablets once daily as necessary.

Follow the directions on the back of the box.

Ask your doctor or pharmacist if you do not understand the instructions on the box.

If your doctor or pharmacist has prescribed CHILDREN'S CLARATYNE, follow the directions given to you by your doctor or pharmacist exactly.

How to take it

Chew the tablet, then swallow.

When to take it

It does not matter if you take CHILDREN'S CLARATYNE before or after food.

How long to take it

Take CHILDREN'S CLARATYNE for up to 5 days, if necessary.

If symptoms persist after 5 days, consult your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (Australia 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much CHILDREN'S CLARATYNE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

## While you are taking CHILDREN'S CLARATYNE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking CHILDREN'S CLARATYNE.

Tell your doctor or pharmacist if you become pregnant while you are taking CHILDREN'S CLARATYNE.

Consult your doctor or pharmacist if your symptoms do not improve.

Your doctor or pharmacist will assess your condition and decide if you should continue to take this medicine.

Things you must not do

Do not take more than the recommended dose

Do not give CHILDREN'S CLARATYNE to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other conditions unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how CHILDREN'S CLARATYNE affects you.

CHILDREN'S CLARATYNE is unlikely to make you drowsy. If you are drowsy, do not drive a car or work with machinery.

Stop taking CHILDREN'S CLARATYNE 48 hours before you have any skin tests. Antihistamines may interfere with the results of skin tests.

### Side effects

All medicine can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of these side effects.

Consult your doctor or pharmacist as soon as possible if you do not feel well while you are taking CHILDREN'S CLARATYNE.

Do not be alarmed by the following lists of side effects.
You may not experience any of them.

Consult your doctor or pharmacist as

Consult your doctor or pharmacist as soon as possible if you notice any of the following:

- hair loss
- · rapid heart rate

The above list includes serious side effects that may require medical attention. These side effects are rare.

Consult your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- · sleepiness
- fatigue
- dry mouth
- nervousness
- fidgeting

- · upset stomach
- diarrhoea
- dizziness

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Other side effects not listed above may occur in some people taking CHILDREN'S CLARATYNE.

# After taking CHILDREN'S CLARATYNE

### Storage

Keep your medicine in the original pack until it is time to take it.

Keep the medicine in a cool dry place where the temperature stays below  $25^{\circ}C.$ 

Do not leave it in the car on hot days or on windowsills.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

## Product description

### What it looks like

CHILDREN'S CLARATYNE tablets are small, purple tablets.

### Ingredients

Each CHILDREN'S CLARATYNE tablet contains:

Active ingredient:

loratadine 5 mg

Inactive ingredients:

- mannitol
- · microcrystalline cellulose
- aspartame
- citric acid
- silicon dioxide
- · sodium starch glycollate
- stearic acid
- magnesium stearate
- · artifical grape flavour
- red 27 aluminium lake
- indigo carmine aluminium lake

Phenylketonurics are warned that CHILDREN'S CLARATYNE contains aspartame (a source of phenylalanine).

### Sponsor

CHILDREN'S CLARATYNE is supplied in Australia by:

Bayer Australia Ltd 875 Pacific Highway, Pymble NSW 2073 Ph: 1800 008 757 www.claratyne.com.au

Australian Registration Number

Children's Claratyne 5 mg Loratadine.

Tablets 10 pack AUST R 295667

Date of Preparation

30 November 2017