

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Lofenoxal?

Lofenoxal contains the active ingredients diphenoxylate hydrochloride and atropine sulfate monohydrate. Lofenoxal is used to for the treatment of acute or chronic diarrhoea.

For more information, see Section [1. Why am I using Lofenoxal?](#) in the full CMI.

2. What should I know before I use Lofenoxal?

Do not use if you have ever had an allergic reaction to diphenoxylate or atropine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Lofenoxal?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lofenoxal and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Lofenoxal?

- The usual starting dose is 2 tablets, three to four times daily, until the diarrhoea is under control.
- The usual maximum dose is 8 tablets in a day (24 hours).

More instructions can be found in Section [4. How do I use Lofenoxal?](#) in the full CMI.

5. What should I know while using Lofenoxal?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Lofenoxal.• Drink plenty of liquids, such as an oral rehydration solution.• Eat as little as possible for the first few days.
Things you should not do	<ul style="list-style-type: none">• Do not give Lofenoxal to children under 12 years of age.
Driving or using machines	<ul style="list-style-type: none">• Make sure you know how you react to Lofenoxal before driving or operating machinery. Lofenoxal can make some people drowsy or dizzy.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while using the medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.• Store away from heat, direct light and steamy or damp places.• Keep out of reach of children. Accidental overdose can lead to severe breathing problems or death.

For more information, see Section [5. What should I know while using Lofenoxal?](#) in the full CMI.

6. Are there any side effects?

Common side effects include nausea and vomiting, stomach upset, drowsiness and dizziness. Serious side effects include severe allergic reactions, severe stomach or bowel problems, fast shallow breathing, fast heartbeat, and a very high temperature.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Lofenoxal[®]

Active ingredients: *diphenoxylate hydrochloride and atropine sulfate monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lofenoxal. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Lofenoxal.**

Where to find information in this leaflet:

- [1. Why am I using Lofenoxal?](#)
- [2. What should I know before I use Lofenoxal?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Lofenoxal?](#)
- [5. What should I know while using Lofenoxal?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Lofenoxal?

Lofenoxal contains the active ingredients diphenoxylate hydrochloride and atropine sulfate monohydrate.

Lofenoxal is an anti-diarrhoeal agent. Diphenoxylate reduces diarrhoea by slowing down the movements of the intestines. Because diphenoxylate may be abused by taking it in doses that are larger than prescribed, a small amount of atropine sulfate is included in LOFENOXAL. This causes unpleasant effects if larger than normal doses are taken and discourages abuse.

Lofenoxal is used to treat short- or long-lasting episodes of diarrhoea when used with other measures such as oral rehydration.

2. What should I know before I use Lofenoxal?

Warnings

Do not use Lofenoxal if:

- You are allergic to diphenoxylate or atropine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have jaundice.
- You have diarrhoea caused by pseudomembranous enterocolitis. This is a potentially serious infection of the gut, which may occur during or up to several weeks following antibiotic treatment.
- You have an inflammatory bowel disease such as ulcerative colitis or Crohn's disease.
- You have bacterial colitis or amoebic colitis.
- It is past the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- Have any other medical conditions, especially
- Liver disease
- Kidney disease
- Down's Syndrome
- A history of drug abuse
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant. Lofenoxal should not be taken near or at the time of giving birth, because diphenoxylate is chemically related to medicines, which can slow down the breathing of newborn infants.

Talk to your doctor if you are breastfeeding or intend to breastfeed. The active ingredients in Lofenoxal may pass into breast milk. Infants of nursing mothers taking Lofenoxal may show some effects of the medicine.

Use in children

- Do not give Lofenoxal to children under 12 years of age.
- Keep Lofenoxal out of reach of children since accidental overdosage may result in severe, even fatal breathing problems.

3. What if I am taking other medicines?

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

Some medicines may interfere with Lofenoxal and affect how it works.

Medicines that Lofenoxal may increase the effect of include:

- Tranquillisers - medicines used to produce calmness, treat anxiety, or help you sleep
- Barbiturates - medicines used to treat epilepsy and to help you sleep.
- Antidepressants - medicines used to treat depression, such as monoamine oxidase inhibitors (MAOI)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lofenoxal.

4. How do I use Lofenoxal?

How much to take

- The usual starting dose is 2 tablets three or four times daily until the diarrhoea is under control.
- Do not take more than 8 tablets in 24 hours.
- After the diarrhoea is under control the dosage may be reduced, so that you are taking just enough tablets to control the diarrhoea. This may be as few as 2 tablets a day. Your doctor will advise you how much to take.
- Your doctor may want you to stop taking Lofenoxal when your bowel movements return to normal.

If you forget to use Lofenoxal

Lofenoxal should be used regularly at the same time each day.

If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Lofenoxal

If you think that you have used too much Lofenoxal, or if a child has accidentally taken Lofenoxal, you should get urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Lofenoxal?

Things you should do

See your doctor straight away if:

- the diarrhoea contains blood or continues for more than 2 days.

Drink plenty of liquids, such as an oral rehydration solution

Drinking plenty of liquids makes sure you do not become dehydrated (lose too much liquid from your body). If you have become very dehydrated, see your doctor to make sure this is corrected, before taking Lofenoxal.

Eat as little as possible for the first few days

Eat only plain, bland foods, such as unbuttered toast, plain biscuits, boiled potatoes, rice, or pasta. Gradually return to your normal diet when the diarrhoea has stopped.

Remind any doctor, dentist, or pharmacist you visit that you are using Lofenoxal.

Things you should not do

- Do not drink alcohol while taking Lofenoxal.
- Do not exceed the recommended dose. Addiction to Lofenoxal is possible at high doses.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lofenoxal affects you.

Lofenoxal may cause dizziness or drowsiness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Lofenoxal may increase the effects of alcohol.

Looking after your medicine

- Store below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Stomach related:</p> <ul style="list-style-type: none"> • Nausea or vomiting • Loss of appetite • Abdominal discomfort <p>Nervous system related:</p> <ul style="list-style-type: none"> • Drowsiness • Dizziness • Confusion • Lacking energy • Depression or euphoria • Headache • Numbness of extremities 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • Rash • Allergic wheals and swelling • Swelling of the gums <p>Signs of atropine poisoning:</p> <ul style="list-style-type: none"> • Unusually high fever • Rapid heartbeat • Unable to urinate • Dry skin and mucous membranes • Flushing of the skin <p>Signs of an overdose:</p> <ul style="list-style-type: none"> • Slow, shallow breathing or abnormally rapid breathing • Pinpoint pupils or other visual changes • Lethargy or coma. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription

What Lofenoxal contains

Active ingredients (main ingredients)	Diphenoxylate hydrochloride Atropine sulfate monohydrate
Other ingredients (inactive ingredients)	sucrose acacia sorbitol talc magnesium stearate liquid paraffin.

Do not take this medicine if you are allergic to any of these ingredients.

What Lofenoxal looks like

Lofenoxal is a white to off-white, uncoated biconvex tablets marked LT on one side.

Registration number: AUST R 74476

Who distributes Lofenoxal

iNova Pharmaceuticals (Australia) Pty Limited

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