Loftenoxal contains diphenoxylate hydrochloride and atropine sulfate along with other ingredients. The 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 Loftenoxal. This causes unpleasant effects if larger than normal doses are taken, and discourages abuse.

Loftenoxal, in pack sizes of 20 tablets, is only available with a doctor’s prescription.

Before you take LOFENOXAL

Before you start to use Loftenoxal

You must tell your doctor if:
- You are allergic to any other medicines, foods, dyes or preservatives
- You may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines that you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking Loftenoxal.
- Do not use alcohol while taking Loftenoxal. Drinking plenty of liquids, such as an oral rehydration solution.

While you are using Loftenoxal

Things you must do
- Use Loftenoxal exactly as your doctor has prescribed.
- Do not drink alcohol or milk. Drinking alcohol or milk can make your diarrhoea worse.
- Do not eat dairy foods, fatty foods such as cakes, pies, chocolates, fatty meats and fried foods, spicy foods, fruit or acidic vegetables. Eating these foods can make your diarrhoea worse.
- Do not take Loftenoxal near or at the time of giving birth, because diphenoxylate is chemically related to medicines which can slow down the breathing of newborn infants.

How to take Loftenoxal

Follow your doctor’s or pharmacist’s instructions exactly on how much Loftenoxal to take and for how long to take it.

The usual starting dose of Loftenoxal is 2 tablets, three or four times a day, until the diarrhoea is under control.

The dose is then usually cut down, so that you are taking just enough tablets to control the diarrhoea. This may be as few as 2 tablets a day. Please check with your doctor as to how you should take Loftenoxal.

The usual maximum dose is 8 tablets in a day (24 hours).

Your doctor may want you to stop taking Loftenoxal when your bowel movements return to normal.

If your diarrhoea contains blood or lasts for more than 2 days, tell your doctor.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (telephone number: 13 11 26) for advice, or go to Casualty at your nearest hospital, if you think that you or anyone else may have taken a large number of Lofenoxal tablets. 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. If you think someone has taken an overdose of Lofenoxal, or if a child has accidentally taken Lofenoxal tablets, you should get medical help immediately.

Keep this leaflet with the medicine. Ask your doctor or pharmacist about Lofenoxal. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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.

Things you must not do
- Do not drink alcohol while taking Loftenoxal.
- Do not take Loftenoxal while breastfeeding, your baby may have some effects from it.
- Do not use this medicine after the by date, which appears on the label after the letters "EXP".
- They may have no effects at all, or an entirely unexpected effect if you use them after the expiry date.
- Do not use Loftenoxal if the packaging is torn or shows signs of tampering.
- Do not use Loftenoxal to treat any other complaints unless your doctor says to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Lofenoxal is not recommended for children less than 12 years old.

Children, especially very young children and those with Down's syndrome, are very sensitive to the effects of Lofenoxal.

Children must be kept out of the reach of children, since accidental overdose in children may result in serious breathing difficulties, or even death.

Keep telephone numbers for these places handy. If you think someone has taken an overdose of Lofenoxal, or if a child has accidentally taken Lofenoxal tablets, you should get medical help immediately.

Signs that may indicate an overdose are: at first, dryness of the skin and mouth, widening of the pupils of the eye, restlessness, flushing, high temperatures and rapid heart beat, followed by lack of energy or coma, poor reflexes, constant movements of the eyeballs, pinpoint (small) pupils and slow, shallow breathing (respiratory depression). Sometimes respiratory depression may not occur straight away, and may develop as late as 30 hours after an overdose. Patients should be watched for at least 48 hours, preferably in hospital.

Before you take Loftenoxal

When you must not use it

Do not take Loftenoxal if you are allergic to:
- diphenoxylate or atropine or any of the tablet ingredients listed at the end of this leaflet.
- You have jaundice.
- You have diarrhoea caused by pseudomembranous enterocolitis (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.
- You are breastfeeding. You should use an alternative form of infant feeding while you are taking Lofenoxal.
- Lofenoxal passes into breast milk, so if you take Lofenoxal while breastfeeding, your baby may have some effects from it.

Lofenoxal is not recommended for children less than 12 years old.

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Side effects
As well as benefits, medicines may have some effects you do not want (side effects). Knowledge of this medicine is continually increasing. Side effects may possibly occur, which were previously unknown, and so this list of possible side effects cannot be complete. It is therefore important to tell your doctor if you experience any unusual side effects or any changes in your health, while you are taking Lofenoxal. Side effects which have been reported in patients taking Lofenoxal are:

- Lack of energy
- Confusion
- Drowsiness
- Dizziness
- Restlessness
- Depression
- Euphoria
- Numbness in hands and feet
- Headache
- Allergic wheals and swelling
- Rash
- Swelling of gums
- Itching
- Vomiting
- Nausea
- Loss of appetite
- Abdominal discomfort
- Severe allergic reaction (anaphylaxis)
- Obstruction or paralysis of the intestine

Reported side effects of atropine sulfate are:

- Unusually high fever
- Rapid heart beat
- Being unable to urinate
- Flushing
- Dry skin and
- Dry mouth

If any side effects do not settle down during treatment and are a problem for you, or if you develop any new medical problem while you are taking Lofenoxal, tell your doctor.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Lofenoxal. Lofenoxal helps most people with diarrhoea, but it may have unwanted effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist about any questions you may have.

Disposal
Carefully dispose of any tablets that are no longer needed or are past the expiry date ("EXP"). Ask your pharmacist for advice on disposal of medicines.

Product description

What it looks like
Lofenoxal tablets are white, uncoated, biconvex tablets marked SEARLE on one side in blister packs of 20 tablets.

Ingredients
They contain 2.5 mg diphenoxylate hydrochloride and 25 micrograms atropine sulfate. Other ingredients in each tablet are: Sucrose, acacia, sorbitol, talc, magnesium stearate, liquid paraffin.

Distributor
Lofenoxal is distributed by: iNova Pharmaceuticals (Australia) Pty Ltd ABN: 88 000 222 408 Level 10, 12 Help Street Chatswood NSW 2067 Tel: 1800 253 272 AUST R 74476 Date of Preparation: 8 Oct 2014

After using Lofenoxal

Storage
Keep it where young children cannot reach it, since overdose is especially dangerous in children.

Do not leave it in the car on hot days.

Keep your tablets in their blister pack until it is time to take them.

Store below 30°C.

Store away from heat, direct light and steamy or damp places. Heat or moisture may cause Lofenoxal tablets to deteriorate.