

# Locacorten®-Vioform

*flumetasone pivalate / clioquinol*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Locacorten-Vioform ear drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Locacorten-Vioform against the benefits they expect it will have for you.

**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 Locacorten-Vioform is used for

Locacorten-Vioform ear drops contain flumetasone pivalate and clioquinol.

Flumetasone pivalate belongs to a group of medicines called corticosteroids. It is used to relieve symptoms of ear infection such as itching, redness and swelling.

Clioquinol is an anti-infective medicine. It is used to fight the germs which are causing the ear infection.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Locacorten-Vioform is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 2 years.

### Before you use Locacorten-Vioform

*When you must not use it*

**Do not use Locacorten-Vioform if you have an allergy to:**

- any medicine containing flumetasone or clioquinol
- any of the ingredients listed at the end of this leaflet.
- other quinoline medicines which are similar to clioquinol
- iodine of other medicines that contain iodine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not use Locacorten-Vioform if you have any of the following medical conditions as it may make your condition worse:**

- a perforated ear drum
- a viral infection of the skin (e.g. chicken pox, cold sores, warts)
- skin infection caused by tuberculosis or syphilis.

**Do not give this medicine to a child under 2 years of age.**

Safety and effectiveness in children younger than 2 years have not been established.

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

*Before you start to use it*

**Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have any other problems with your ear or you have other skin infections.**

Your doctor may want to take special precautions in that case.

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you experience blurred vision or other visual disturbances.**

**If you have not told your doctor about any of the above, tell him/her before you start using Locacorten-Vioform.**

*Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop (e.g. other ear drops).**

Some medicines and Locacorten-Vioform may interfere with each other. You may need different amounts of your medicines or you may need to take different medicines.

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

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## How to use Locacorten-Vioform

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### *How much to use*

You will usually use two or three drops in the affected ear twice a day.

### *How to use the drops*

**Unless your doctor gives you other instructions, follow these directions:**

- Wash your hands with soap and water, then carefully clean and dry the inside of your ear.
- Warm the ear drops to body temperature by holding the bottle in your hand for a few minutes. Do not heat the drops in hot water because they may get too hot and cause pain and dizziness.
- Either sit and tilt your head or lie down so that the ear you are treating is facing up.
- Gently pull the top of the ear up and back. This helps to straighten the ear canal so the ear drops can reach the eardrum.
- Hold the dropper above the ear canal and gently squeeze the plastic bottle until the right number of drops go into the

canal. Do not touch the dropper against the ear, your fingers or any other surface. Do not put the dropper into the ear canal as it may cause injury.

- Stay in the same position for 1 or 2 minutes to let the drops run down inside the ear.
- If you have to put ear drops into both ears, wait 5 or 10 minutes after the first ear before placing drops into the second ear. This keeps the drops in the first ear from running out.
- Alternatively, use a piece of gauze or cotton wick then soak with the ear drops and place it inside the ear.

**Try to keep the ear drops from running out of your ear.**

The ear drops may stain hair, clothing and bed linen yellow.

**If you accidentally get some of the drops in your eyes, flush them at once with plenty of cold water.**

The active ingredients in the ear drops could hurt your eyes.

### *How long to use them*

Locacorten-Vioform ear drops should give you fast relief from any itchiness, redness and swelling of your ear. Treatment usually should not last longer than 10 days.

**If there is no improvement or if your symptoms become worse after you have used the drops for one week, tell your doctor.**

### *If you forget to use them*

**If it is almost time for your next dose, skip the dose you missed and use the drops when you are next meant to.**

**Otherwise, use them as soon as you remember, and then go back to using them as you would normally.**

**Do not use a double dose to make up for the one that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you have trouble remembering when to use the drops, ask your pharmacist for some hints.**

### *If you use too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Locacorten-Vioform. Do this even if there are no signs of discomfort or poisoning.**

It is unlikely that an overdose will happen if this medicine is used correctly. But, if it is used on large areas of broken skin, placed in the eye or swallowed, it could cause unwanted side effects.

If this medicine is swallowed by children, it can cause stomach upset, nausea and vomiting.

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## While you are using Locacorten-Vioform

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### *Things you must do*

**If your ear problem seems to be getting worse, tell your doctor.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Locacorten-Vioform.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are using Locacorten-Vioform.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while using Locacorten-Vioform, tell your doctor immediately.**

Your doctor can decide if treatment should continue.

**If you are going to have any tests on your thyroid, tell the person doing the test that you are using Locacorten-Vioform.**

This medicine can interfere with the results of some thyroid tests.

### *Things you must not do*

**Do not use any other medicines for your ears without first telling your doctor.**

Using other medicines together with Locacorten-Vioform could cause unwanted side effects.

**Do not use Locacorten-Vioform to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop using it, your condition may worsen.

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### Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Locacorten-Vioform.**

This medicine helps most people with ear infections, but it may have unwanted side effects in a few people. All medicines can 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.

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

**Ask your doctor or pharmacist to answer any questions you may have.**

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

- ear irritation such as a burning sensation, redness, itching or rash on the ear
- blurred vision
- thinning of the skin
- skin infection.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- serious allergic reaction (shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin).

This is a very serious side effect.

You may need urgent medical attention or hospitalisation. This side effect is very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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### After using Locacorten-Vioform

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#### *Storage*

**Keep your ear drops in a cool dry place where the temperature stays below 25°C.**

**Do not store Locacorten-Vioform or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**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*

**If your doctor tells you to stop using the ear drops or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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### Product description

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#### *What it looks like*

Locacorten-Vioform ear drops come in a plastic dropper bottle containing 7.5 mL of clear, thick yellowish solution.

### *Ingredients*

Locacorten-Vioform ear drops contain flumetasone pivalate 200 micrograms/mL and clioquinol 10 mg/mL as the active ingredients.

They also contain macrogol 300.

### *Sponsor*

Locacorten-Vioform is supplied in Australia by:

Amdipharm Mercury (Australia) Pty Ltd

Level 9, 76 Berry Street  
North Sydney NSW 2060

#### **Date of preparation:**

4 August 2017

#### **Australian Registration Number:**

AUST R 11040

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