

Locorten[®] Vioform[®] Ear Drops solution

(flumetasone pivalate/clioquinol)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Locorten Vioform ear drops are and what they are used for
2. What you need to know before you use Locorten Vioform ear drops
3. How to use Locorten Vioform ear drops
4. Possible side effects
5. How to store Locorten Vioform ear drops
6. Contents of the pack and other information

1. WHAT LOCORTEN VIOFORM EAR DROPS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Locorten Vioform ear drops. Locorten Vioform ear drops contain the active ingredients Flumetasone pivalate and Clioquinol.

Locorten Vioform ear drops are used to treat infection and inflammation of the external ear.

The drops contain an antibacterial and antifungal ingredient to combat infection and a steroid which acts to reduce inflammation.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LOCORTEN VIOFORM EAR DROPS

Do not use Locorten Vioform ear drops:

- if you are **allergic** to flumetasone pivalate, clioquinol or any of the other ingredients of this medicine (listed in section 6). Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing;
- if you have a perforated or burst ear drum;
- if you have an infection of the outer ear.

Locorten Vioform ear drops should not be used on children under 2 years.

If any of the above apply to you or if you are not sure, tell your doctor or pharmacist before using the ear drops.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Locorten Vioform ear drops.

Tell the doctor you are using Locorten Vioform ear drops if you have any thyroid or urine tests. This is because Locorten Vioform ear drops may affect the results.

Long term-continuous use should be avoided because it can lead to hormonal suppression (the maximum duration of therapy recommended is 7-10 days).

Some medicines may increase the effects of Locorten Vioform ear drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

Other medicines and Locorten Vioform ear drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those you have obtained without a prescription.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You **should not** use Locorten Vioform ear drops if you are pregnant, planning to become pregnant or if you are breast-feeding unless your doctor feels it is necessary.

3. HOW TO USE LOCORTEN VIOFORM EAR DROPS

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 2 or 3 drops twice a day, for up to 7–10 days.

Your specific dosage will be given on the carton label.

Use in children and adolescents

Locorten Vioform ear drops should not be used in children under the age of two.

Method of administration

Sit or lie down with the affected ear uppermost.

Place the nozzle of the bottle near the ear opening and squeeze the middle of the bottle with your fingers. (You may find it easier to ask someone else to do this for you.)

Remain with your head tilted for a few minutes; it may be helpful to place a piece of cotton wool loosely in the ear opening for a short period to stop any drops running out.

Be careful not to get the ear drops in or near the eye.

Wash your hands after applying the ear drops.

If you forget to use Locorten Vioform ear drops

If you forget to use a dose, put in the drops as soon as you remember and then continue as before. Do not apply a double dose to make up for a forgotten dose.

If the ear drops are accidentally **swallowed**, contact your doctor or go to your nearest hospital emergency department **immediately**.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice;

- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness.

Stop using the ear drops and tell your doctor immediately. These may be signs of an allergic reaction.

Locorten Vioform ear drops can cause irritation in or on the ear. Signs of this might be: burning; itching or rash. The drops may also cause discolouration of the skin or hair.

Not known (frequency cannot be estimated from the available data):

- Blurred vision

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LOCORTEN VIOFORM EAR DROPS

- **Keep out of the sight and reach of children.**
- Store your ear drops in a safe place.
- Store in original package. Do not store above 25°C.
- Do not use Locorten Vioform Ear Drops after the "expiry date" which is stated on the carton and bottle. The expiry date refers to the last day of that month.

- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If your medicine have become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Locorten Vioform Ear Drops may stain clothing and bed clothes yellow. If this occurs, then the items should be washed within 24 hours, if possible. Fabrics suitable for soaking should be soaked overnight. After soaking, boil, or if not suitable for boiling, wash at the temperature recommended for the fabric (see the fabric label). It is advisable to use a soap based powder.

The drops may also discolour jewellery if they come into contact.

What Locorten Vioform Ear Drops contain

Contains 0.02% w/v flumetasone pivalate and 1% w/v clioquinol. Also contains macrogol 300.

What Locorten Vioform Ear Drops looks like and the contents of the pack.

Clear, yellowish to brownish-yellow solution in a yellow plastic dropper bottle with a black cap and containing 7.5 ml solution.

Manufacturer: Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

Procured from within the EU & repackaged by

PL holder: Kosei Pharma UK Limited., 956 Buckingham Avenue, Slough, SL1 4NL, UK

**Locorten® Vioform® Ear Drops solution
PL 39352/0377**

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Leaflet date: 08/09/2017

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**To listen to or request a copy of this leaflet in Braille, large print or audio please call:
01753515054 (UK only)**

Flumetasone pivalate/Clioquinol 0.02% w/v/1% w/v Ear Drops, solution

(flumetasone pivalate/clioquinol)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Flumetasone pivalate/Clioquinol 0.02% w/v/1% w/v Ear Drops solution; it will be called Flumetasone/Clioquinol Ear Drops for ease here after.

What is in this leaflet

1. What Flumetasone/Clioquinol Ear Drops are and what they are used for
2. What you need to know before you use Flumetasone/Clioquinol Ear Drops
3. How to use Flumetasone/Clioquinol Ear Drops
4. Possible side effects
5. How to store Flumetasone/Clioquinol Ear Drops
6. Contents of the pack and other information

1. WHAT FLUMETASONE/CLIOQUINOL EAR DROPS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Flumetasone/Clioquinol Ear Drops.

Flumetasone/Clioquinol Ear Drops contain the active ingredients Flumetasone pivalate and Clioquinol.

Flumetasone/Clioquinol Ear Drops are used to treat infection and inflammation of the external ear.

The drops contain an antibacterial and antifungal ingredient to combat infection and a steroid which acts to reduce inflammation.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUMETASONE/CLIOQUINOL EAR DROPS

Do not use Flumetasone/Clioquinol Ear Drops:

- if you are **allergic** to flumetasone pivalate, clioquinol or any of the other ingredients of this medicine (listed in section 6). Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing;
- if you have a perforated or burst ear drum;
- if you have an infection of the outer ear.

Flumetasone/Clioquinol ear drops should not be used on children under 2 years.

If any of the above apply to you, or if you are not sure, tell your doctor or pharmacist before using the ear drops.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Flumetasone/Clioquinol ear drops.

Tell the doctor you are using Flumetasone/Clioquinol ear drops if you have any thyroid or urine tests. This is because Flumetasone/Clioquinol ear drops may affect the results.

Long term-continuous use should be avoided because it can lead to hormonal suppression (the maximum duration of therapy recommended is 7-10 days).

Some medicines may increase the effects of Flumetasone/Clioquinol ear drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

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You **should not** use Flumetasone/Clioquinol ear drops if you are pregnant, planning to become pregnant or if you are breast-feeding unless your doctor feels it is necessary.

3. HOW TO USE FLUMETASONE/CLIOQUINOL EAR DROPS

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 2 or 3 drops twice a day, for up to 7–10 days.

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Use in children and adolescents

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The drops may also discolour jewellery if they come into contact.

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What Flumetasone/Clioquinol Ear Drops looks like and the contents of the pack.

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Manufacturer: Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

Procured from within the EU & repackaged by PL holder: Kosei Pharma UK Limited, 956 Buckingham Avenue, Slough, SL1 4NL, UK

Flumetasone pivalate/Clioquinol 0.02% w/v/ 1% w/v Ear Drops, solution

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