**Locorten® Vioform Ear Drops**
(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. The name of your medicine is Locorten Vioform Ear Drops but will be referred to as Locorten Vioform Ear Drops or just ear drops throughout the remainder of this leaflet.

**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 applies 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.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 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**
The active ingredients in Locorten Vioform Ear Drops are flumetason pivalate 0.02% w/v and clioquinol 1% w/v.

Each ml contains 0.02% w/v flumetasone pivalate and 1% w/v clioquinol.

Also contains macrogol.

**What Locorten Vioform Ear Drops look like and the contents of the pack**
Locorten Vioform Ear Drops is a clear yellow solution which comes in a 7.5ml plastic bottle.

Manufactured by
Laboratorio Italiano Biochimico Farmaceutico Lisapharma S.p.A.,
Via Licinio, 11, 22036 Erba, (CO) Italy.

Procured from within the EU by the Product Licence Holder:
MPT Pharma Ltd. Westgate Business Park, Unit 5-7 Tintagel Way,
Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

PL: 33532/0752

Leaflet dated 27th June 2017
Leaflet coded xxxxxxxxxxxx

Locorten® is a registered trademark of Novartis AG.

To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.
Package Leaflet: Information for the User

Flumetasone Pivalate/Clioquinol 0.02% w/v / 1% w/v Ear Drops solution

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.
- The name of your medicine is Flumetasone Pivalate/Clioquinol 0.02% w/v / 1% w/v Ear Drops solution but will be referred to as Flumetasone/Clioquinol Ear Drops or just ear drops throughout the remainder of this leaflet.

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 applies 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.

Other medicines and Flumetasone/Clioquinol 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 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. Your specific dosage will be given on the carton label.

Use in children and adolescents
Flumetasone/Clioquinol 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 Flumetasone/Clioquinol 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.

Flumetasone/Clioquinol 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 Flumetasone/Clioquinol Ear Drops

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

Flumetasone/Clioquinol 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 Flumetasone/Clioquinol Ear Drops contain
The active ingredients in Flumetasone/Clioquinol Ear Drops are flumetasone pivalate 0.02% w/v and clioquinol 1% w/v.

Each ml contains 0.02% w/v flumetasone pivalate and 1% w/v clioquinol.

Also contains macrogol.

What Flumetasone/Clioquinol Ear Drops look like and the contents of the pack
Flumetasone/Clioquinol Ear Drops is a clear yellow solution which comes in a 7.5ml plastic bottle.

Manufactured by Laboratorio Italiano Biochimico Farmaceutico Lisapharma S.p.A., Via Licinio, 11, 22036 Erba, (CO) Italy.

Procured from within the EU by the Product Licence Holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

PL: 33532/0752 POM

Leaflet dated 27th June 2017
Leaflet coded xxxxxxxxxxxx

To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.