

Package leaflet: Information for the user

Flumetasone/Clioquinol 0.02% w/v/ 1% w/v Ear Drops Solution flumetasone pivalate and 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 Flumetasone/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
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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 inflammation of the external ear where a secondary infection is suspected.

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 to 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.

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.

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.

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 take 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store your ear drops in a safe place. Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 substances are flumetasone pivalate 0.02% w/v and clioquinol 1% w/v.
- The other ingredient is polyethylene glycol.

What Flumetasone/Clioquinol Ear Drops look like and the content of the pack.

Flumetasone/Clioquinol Ear Drops is clear, yellowish to brownish-yellow solution. The drops come in a plastic dropper bottle containing 7.5 ml or 10 ml of drops.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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