

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- This medicine is available without prescription. However, you still need to use Hydrocortisone 2.5mg Buccal Tablets carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after five days.
- In this leaflet Hydrocortisone 2.5mg Muco-Adhesive Buccal Tablets will be called Hydrocortisone 2.5mg Buccal Tablets.

What is in this leaflet:

- 1. What Hydrocortisone 2.5mg Buccal Tablets are and what they are used for**
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1. What Hydrocortisone 2.5mg Buccal Tablets are and what they are used for

Hydrocortisone 2.5mg Buccal Tablets belong to a group of medicines called corticosteroids.

Hydrocortisone 2.5mg Buccal Tablets work by reducing any swelling and inflammation in your mouth.

Hydrocortisone 2.5mg Buccal Tablets are used to treat mouth ulcers. Only use this medicine if:

- Your doctor or dentist has told you to.
 - You know you have a condition called recurrent aphthous ulceration.
- You must not use Hydrocortisone 2.5mg Buccal Tablets to treat ulcers caused by either wearing dentures or from an injury or infection. You must see your doctor or dentist about getting treatment for these.

You must not use Hydrocortisone 2.5mg Buccal Tablets for the treatment of impaired adrenal glands, where they do not produce a sufficient amount of steroid hormones.

Hydrocortisone 2.5mg Buccal Tablets contain a different type of steroid to those misused by sports people.

2. What you need to know before you use Hydrocortisone 2.5mg Buccal Tablets

Do not use Hydrocortisone 2.5mg Buccal Tablets if:

- You are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- You have an infection in your mouth.

If any of the above applies to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Hydrocortisone 2.5mg Buccal Tablets if:

- You keep getting ulcers or they become severe.
- You are taking any other medicines, including those without a prescription.
- If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

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

Other medicines and Hydrocortisone 2.5mg Buccal Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Some medicines may increase the effects of Hydrocortisone 2.5mg Buccal Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)

Pregnancy and breast-feeding

There may be a small chance that this medicine may harm an unborn baby.

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.

Hydrocortisone 2.5mg Buccal Tablets contain lactose

Hydrocortisone 2.5mg Buccal Tablets contain 68mg of lactose per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Hydrocortisone 2.5mg Buccal Tablets

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

Adults and Elderly

Adults using this medicine should follow the instructions given below.

If you do not understand the instructions or you are not sure, ask your doctor or pharmacist.

- Do not suck Hydrocortisone 2.5mg Buccal Tablets.
- Put one tablet as near to the ulcer as you can and let it dissolve.
- If you have more than one ulcer, swap the tablet from one ulcer to another. Do not use more than one tablet at a time.
- Use one tablet, four times each day, for up to five days. This is a treatment course.
- If the ulcers heal you can stop using the medicine.

Remember: if after 5 days treatment, the ulcers have not healed or more come back soon after finishing the course, you must see your doctor.

Use in children

Children using this medicine should follow the instructions given by their doctor.

Children under 12 years

- Children under 12 years must see a doctor before starting each course of Hydrocortisone 2.5mg Buccal Tablets.
- Your doctor will tell you the correct way for a child to use this medicine.

If you use more Hydrocortisone 2.5mg Buccal Tablets than you should

If you accidentally use too many Hydrocortisone 2.5mg Buccal Tablets, contact the nearest hospital casualty department or your doctor as soon as possible.

If you forget to use Hydrocortisone 2.5mg Buccal Tablets

Do not use a double dose to make up for a forgotten dose.

Simply use the next dose as planned. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Hydrocortisone 2.5mg Buccal Tablets can cause side effects, although not everybody gets them.

Only use this medicine for as short a time as possible.

Only use it directly on the ulcers. This will lower the chance of getting any side effects.

Serious side effects:

If you experience any of the following side effects, **stop using Hydrocortisone 2.5mg Buccal Tablets and contact your doctor immediately.**

- Allergic reactions.
- If you have diabetes, it may get worse.
- If you have an infection in your mouth, it may get worse.
- Blurred vision (not known: frequency cannot be estimated from the available data).
- Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies (not known: frequency cannot be estimated from the available data).

Other side effects:

The following side effect has also been reported with corticosteroid medicines like Hydrocortisone 2.5mg Buccal Tablets:

- Weight increased (not known: frequency cannot be estimated from the available data).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 Hydrocortisone 2.5mg Buccal Tablets

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/carton/bottle. The expiry date refers to the last day of that month. Store below 25°C. Replace the cap firmly after use.

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

What Hydrocortisone 2.5mg Buccal Tablets contain

The active substance is 2.5mg hydrocortisone.

The other ingredients are lactose, acacia and magnesium stearate.

What Hydrocortisone 2.5mg Buccal Tablets look like and contents of the pack

Hydrocortisone 2.5mg Buccal Tablets are small white tablets with 'Corlan Evans' written on one side.

Hydrocortisone 2.5mg Buccal Tablets come in plastic containers with 20 tablets.

Marketing Authorisation Holder

Accord Healthcare Limited, Sage House, 319 Pinner Road
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Manufacturer

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Medical Information at Accord, Whiddon Valley, Bamstaple, North Devon, EX32 8NS, UK.