KANOLONE[®] Oral Base

Triamcinolone Acetonide 0.1 %

- 1. What KANOLONE[®] Oral Base is used for
- 2. How KANOLONE[®] Oral Base works
- 3. Before you use KANOLONE® Oral Base
- 4. How to use KANOLONE[®] Oral Base
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of KANOLONE® Oral Base
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision
- 11. Serial number

1. What is KANOLONE[®] Oral Base used for

KANOLONE Oral Base is used for relieving tenderness, pain, inflammation and ulceration of the inside of the mouth or the gums.

KANOLONE Oral Base is used to treat inflamed mouth sores and mouth sores caused by injury. This can include sores caused by dentures (false teeth) rubbing on the gums.

2. How KANOLONE[®] Oral Base works

KANOLONE Oral Base contains active ingredient called Triamcinolone Acetonide, which belongs to a class of drugs known as corticosteroids.

It acts by decreasing inflammation and protecting the damaged area from further injury. The sticky paste keeps the medicine on the on the sore area and protects it while the medicine relieves the soreness, reduces the swelling and accelerates the healing process.

3. Before you use KANOLONE[®] Oral Base

When you must not use it

- Do not use KANOLONE Oral Base if you have an allergy to

Triamcinolone Acetonide or any of the additional ingredients this medicine contains.

There exist viral (such as herpes), fungal and/or bacterial infections of the mouth and/or throat or tuberculosis of the skin, especially during prolonged use of the preparation.
Do not use KANOLONE Oral Base if you are pregnant or intend to become pregnant, unless you have discussed this with a doctor.

Before you start to use it

Tell your doctor, dentist or pharmacist if you:

- Are pregnant or may become pregnant
- Are allergic to any food or drugsHave any infections in the mouth or
- throat, especially herpes (cold sores) - Have tuberculosis (TB), stomach
- ulcers or diabetes - Take any other medications or drugs

Taking other medications

It is unlikely that other medicines will affect the way KANOLONE Oral Base works. Nevertheless, you should tell your doctor, dentist or pharmacist about other medicines you are taking, even if those medicines have been bought without a prescription.

4. How to use KANOLONE[®] Oral Base

How much to use

It is applied directly to the affected areas of the mouth.

Dab or press (do not rub) a small amount of paste onto the area to be treated until the paste sticks and a smooth, slippery film develops.

A cotton swab may be used to apply the paste. Do not attempt to spread or rub the paste in. This will only cause it to become crumbly, grainy, or gritty. Apply to the affected area 2 to 3 times daily after meals or at bedtime as directed by your doctor or dentist.

The treated area should not be bandaged or otherwise covered or wrapped unless your doctor or dentist directs you to do so.

Mouth infections may worsen while you are using this medication. Inform

the prescribing doctor or dentist if your condition persists or worsens after 7-14 days of treatment.

When to use it

Apply the preparation at bedtime, to allow the medication to work overnight. Sometimes it may be necessary to apply the preparation two or three times a day, preferably after meals.

How long to use it

Use KANOLONE Oral Base until all symptoms have resolved or for as long as your doctor, pharmacist or dentist tells you to.

If you forget to use it

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Use your next dose at the regular time. Do not double the dose to catch up.

If you use too much (overdose)

Overdose with this medication is unlikely even if swallowed. However, if someone has overdosed and has serious symptoms such as passing out or trouble breathing, contact your doctor or accident and emergency department immediately.

5. While you are using it

Things you must do

Tell your doctor if you become pregnant while you are using this medicine.

Stop using it if the condition is getting worse, or if you feel any weakness or dizziness while using it. Speak to your doctor or pharmacist if you notice any of these things.

Wipe the neck of the tube and replace the cap tightly after use.

If local irritation or sensitization should develop, the preparation should be discontinued and appropriate therapy instituted.

Things you must not do

You should not swallow
KANOLONE Oral Base
You should not put KANOLONE
Oral Base in your eyes.

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- Do not share this medicine with another person, even if they have the same symptoms you have.

Things to be careful of

Be careful driving or operating machinery until you know how KANOLONE Oral Base affects you.

6. Side effects

All medicines can sometimes cause unwanted effects. Side effects of KANOLONE Oral Base are extremely rare.

The side effects that may occur include:

- Worsening of sores inside the mouth

- New patches of irritation or sensitivity inside the mouth

- Weakness or dizziness.

If corticosteroids are used for long periods during pregnancy, the mother may develop fluid retention or the baby may be affected. However, these effects occur very rarely and usually with much higher doses of corticosteroids than the amount of Triamcinolone Acetonide in KANOLONE Oral Base

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <u>npra gov.my</u> [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of KANOLONE® Oral Base

<u>Storage</u> Store below 30°C.

Disposal

If your doctor, pharmacist or dentist tells you to stop using KANOLONE Oral Base, or if the ointment has passed its expiry date, ask your pharmacist what to do with any that is left over.

8. Product Description

<u>What it looks like</u>

Homogeneous, light brown paste.

Ingredients

Active ingredient(s)

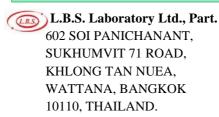
Triamcinolone Acetonide

Inactive ingredient(s)

Benzyl alcohol Gelatin Carboxymethylcellulose Sodium Polyethylene excipient Liquid Paraffin Pectin Peppermint oil Menthol

MAL number MAL 20012698AZ

9. Manufacturer



Product Registration Holder

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