

ORREGEL

Choline Salicylate / Cetylpyridinium Chloride (8.7%w/w / 0.1%w/w)

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This leaflet answers some common questions about Orregel. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Orregel against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What Orregel is used for

Orregel is used to relieve pain and discomfort in infant teething, transient mouth ulcers, sore gums, palate, lips and denture pressure sore.

How Orregel works

Orregel contains the active ingredients Choline Salicylate and Cetylpyridinium Chloride.

Choline Salicylate is a non-steroidal anti-inflammatory drug (NSAID) used to relieve pain and discomfort.

Cetylpyridinium Chloride is an antiseptic that works to kill bacteria and other microorganisms.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Orregel

-When you must not use it

Do not apply Orregel if:

- You are allergic (hypersensitive) to salicylates or to any of the other ingredients in this medicine.
- You are suffering from a stomach ulcer.

-Before you start to use it

Pregnancy and breast feeding:

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Orregel

-How much to use

Children (above 4 months of age): Wipe surface free from mucus before application. Using a clean finger, gently massage a small amount of the gel onto the sore area.

Not to be used in infants under 4 months of age.

-When to use it

Apply when experiencing teething discomfort, mouth ulcers, sore gums, palate and lips, and denture pressure sores.

-How long to use it

This may be used not more than once every 3 hours to a maximum of 6 times a day.

-If you forget to use it

Take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time.

Do not take a double dose to make up for the one you have missed.

-If you use too much (overdose)

No information is available concerning overdosage in human beings.

While you are using Orregel

-Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Orregel.

-Things you must not do

Do not take more than the recommended dose unless your doctor or dentist tells you to.

Do not give aspirin preparations to children under 12 years old during treatment using Orregel.

-Things to be careful of

Preparation containing salicylates may precipitate bronchospasm (sudden constriction of the muscles in the walls of the airway) and induce attacks of asthma in susceptible individuals.

Side effects

Like other medicines, Orregel can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

There are no known side effects from Orregel. However, if you think the gel is causing the baby any problems, please consult your doctor or pharmacist.

Stop taking the medicine if you experience: any symptoms of allergy (hypersensitivity).

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problem / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Orregel

-Storage

Store below 30°C.

Keep the tube well closed.

Protect from strong light.

Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date. 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.

Product description

-What it looks like

Orregel is a translucent gel with a blackcurrant flavour. It is alcohol-free with no added sugar.

Orregel is available in aluminium tubes 5g and 15g.

-Ingredients

-Active ingredient(s):

Each tube contains Choline

Salicylate 8.7% w/w and

Cetylpyridinium Chloride

0.1% w/w.

-Inactive ingredients:

Blackcurrant Flavour,

Carboxymethyl cellulose,

Methylparaben, Sodium

Polyacrylate, Pectin,

Propylparaben, Sorbitol Solution

70%, Purified Water.

-MAL number:

MAL20014237X

Manufacturer

HOE Pharmaceuticals Sdn. Bhd.

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Bandar Sultan Suleiman,

42000 Port Klang, Selangor,

Malaysia.

Product Registration Holder:

HOE Pharmaceuticals Sdn. Bhd.

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