

SIGMACORT® 1% cream and ointment

hydrocortisone acetate

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of using SIGMACORT against the benefits this medicine is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What is SIGMACORT

The name of your medicine is SIGMACORT. It contains the active ingredient called hydrocortisone acetate.

It is available as a cream and an ointment.

SIGMACORT is a type of cortisone and belongs to the group of medicines called corticosteroids.

It is a topical corticosteroid therapy for non-infective inflammatory conditions of the skin e.g. eczema, dermatitis. It is used to relieve the redness, swelling, itching and other discomforts of the skin.

Your doctor however, may have prescribed SIGMACORT for another purpose.

Ask your doctor or pharmacist if you have any questions about why SIGMACORT has been prescribed for you.

A doctor's prescription is required for the 50 gram tube of SIGMACORT cream or ointment.

The 30 gram tube can be purchased without a doctor's prescription.

Before you use it

When you must not use it

Do not use SIGMACORT if you have ever had an allergic reaction to:

- SIGMACORT or hydrocortisone acetate.
- Any of the ingredients in SIGMACORT listed at the end of this leaflet.

Do not use SIGMACORT if you have:

- A viral skin infection (such as herpes simplex, cold sores, shingles or chicken pox)
- A fungal skin infection (such as thrush, tinea or ringworm)
- Tuberculous condition of the skin
- Vaccinia (cowpox: a viral disease passed from cattle)
- Varicella (a rare form of chicken pox).

SIGMACORT should not be used if you suffer from poor circulation of blood in the skin region, as it may result in skin ulcers.

Occlusive dressings should not be used if you have a skin infection.

Ask your doctor or pharmacist to be sure that you do not have any of these conditions.

Do not use SIGMACORT after the expiry date printed on the pack.

It may have no effect at all, or worse, it may give an entirely unexpected effect if you use after the expiry date.

Do not use it if the packaging shows sign of tampering or the seal on the tube is broken, or if the product does not look quite right.

Before you start to use it

You must tell your doctor if:

- You are allergic to any other medicines, foods, dyes or preservatives.
- You have any other health problems
- You are pregnant or breast-feeding.

Do not apply SIGMACORT to the breast before breast-feeding.

Using other medicines

Tell your doctor or pharmacist if you are using other creams, ointments or lotions or taking any medicine.

This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with SIGMACORT if it is used

excessively or for prolonged periods.

Your doctor or pharmacist has a list of medicines that may interfere with SIGMACORT.

If you have not told your doctor about any of the above, tell them before you start using SIGMACORT.

Use in Children

Do not use in children unless your doctor tells you to do so.

How to use it

How to use it

Apply a thin smear to affected areas two to four times a day or as directed.

Occlusive dressings are not necessary unless advised by your doctor.

It is important to use SIGMACORT exactly as your doctor or pharmacist has told you.

If you use it less than you should, it may not work as well and your skin problem may not improve.

Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

Use SIGMACORT at the same time every day.

How long to use it

Your doctor or pharmacist will tell you how long to use SIGMACORT.

Reduce the number of applications as the disorder subsides.

If you use SIGMACORT for a long time, the chance of side effects increases.

If you forget to use it

If you forget to use SIGMACORT, use it as soon as you remember and then go back

to your normal times for application.

Do not try to make up for the amount you missed by using more than you normally use.

If you swallow it

Telephone your doctor or the Poisons Information Centre (phone 13 11 26) for advice or go to the Accident and Emergency Centre at your nearest hospital immediately if you or anyone you know swallows SIGMACORT.

While you are using it

Things you must do

Tell all your doctors and pharmacists who are treating you that you are using SIGMACORT.

Tell your doctor if you feel that SIGMACORT is not helping your condition.

Tell your doctor if, for any reason, you have not used SIGMACORT exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you become pregnant while using SIGMACORT.

Things you must not do

Do not use SIGMACORT under dressings or on large areas of skin unless your doctor tells you.

Do not use it in or near the eyes.

Do not give SIGMACORT to anyone else even if their symptoms seem similar to yours.

Do not use SIGMACORT to treat other conditions unless your doctor tells you.

Your doctor has prescribed SIGMACORT especially for you and your condition. If you use it for another condition, it may not work or make the condition worse.

Things to be careful of

Do not use large amounts of SIGMACORT for a long time.

If you use large amounts for long time, the chance of systemic absorption through the skin and the chance of side effects increase.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using this medicine.

Only use SIGMACORT under the arm or in the groin if your doctor tells you.

Side Effects

Tell your doctor or pharmacist if you do not feel well while you are using SIGMACORT.

This medicine helps most people with skin problems but it may have some unwanted side effects in a few people.

Side effects reported by some people using SIGMACORT include:

- itching
- burning
- dryness
- acne-form eruptions.

In addition to the above side effects prolonged or over-use of this product may cause the following side effects in some people:

- high blood pressure
- elevated cholesterol and triglyceride levels in the blood
- cataracts
- glaucoma.

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

If you have any other side effects, check with your doctor.

After using it

Storage

Keep your medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep SIGMACORT in a cool dry place where the temperature stays below 25°C.

Do not leave it in the car or on windowsills.

Heat can destroy some medicines.

Disposal

If your doctor tells you to stop using SIGMACORT or it has passed its expiry date, ask your pharmacist what to do with any left over.

- hard paraffin
- liquid paraffin
- wool fat.

SIGMACORT ointment is preservative free.

The Australian Product Registration numbers are:

SIGMACORT cream: AUST R 19778

SIGMACORT ointment: AUST R 19779.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

This leaflet was revised in September 2017.

Product description

What it looks like

SIGMACORT cream is a soft white cream with faint odour of chlorocresol.

SIGMACORT ointment is a soft, yellowish-white ointment with a faint odour of paraffin and lanolin.

Both SIGMACORT cream and ointment are packed in 30 g and 50 g tubes.

Ingredients

Hydrocortisone acetate (microfined) 1% or 10 mg/g is the active ingredient in both SIGMACORT cream and ointment.

Inactive Ingredients

SIGMACORT cream:

- white soft paraffin
- liquid paraffin
- cetomacrogol 1000
- cetostearyl alcohol
- chlorocresol (preservative).

SIGMACORT ointment:

- white soft paraffin