SUPRIAD® OINTMENT, FATTY OINTMENT, CREAM & LOTION

Methylprednisolone aceponate (meth'il-predd-niz-oh-lone ass-epp-on-eight)

Consumer Medicine Information

Please read this leaflet carefully before you start your treatment. Keep this leaflet. You may want to read it again.

What is in this leaflet?

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Supriad® against the benefits it is expected to have for you.

If you have any concerns about using Supriad®, talk to your doctor or pharmacist.

What Supriad® is used for

The active ingredient in Supriad® belongs to the group of medicines called corticosteroids. The corticosteroid in Supriad® is suitable to put on the skin. It is therefore called a topical corticosteroid, which is sometimes shortened to topical steroid.

When Supriad® is put on the skin, it relieves the redness, swelling, itching and irritation of the skin in **eczema and psoriasis**.

Supriad® preparations are available only with a doctor's prescription.

Supriad® is made up as four different preparations. Each has a distinct look and feel. They are:

- ointment
- fatty ointment
- · cream and
- lotior

The most solid is the fatty ointment; the most runny is the lotion. The ointment and cream are in-between in thickness.

Each preparation is especially suitable in consistency for a particular area of skin or skin condition needing treatment. Your doctor will prescribe the preparation most suitable for you.

The Supriad® preparations are medicines and should only be used on skin affected by the conditions described below.

All four Supriad® preparations treat **eczema**. Supriad® ointment, fatty ointment and cream (but NOT lotion) also treat psoriasis.

Eczema is a skin condition with redness, swelling, oozing of fluid, crusting and later scaling. It is often very itchy.

Psoriasis is a skin disorder with raised, rough, reddened areas covered with dry, fine, silvery scales.

Your doctor may have prescribed Supriad® for another reason. Discuss this with him/her. Supriad® is not addictive. It is not expected to affect your ability to drive a car or operate machinery.

Before you use Supriad®

When you must not use Supriad® Do not use Supriad® if you have an allergy to:

 any medicine containing methylprednisolone aceponate

- any of the ingredients listed at the end of this leaflet (see Product description).
- any other similar medicine, that is, topical corticosteroids.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Supriad® if in the area of skin you are treating:

- you have infection due to
 - tuberculosis (TB) or syphilis
 - a virus such as chicken-pox or shingles
 - a skin reaction following a vaccination.

Do not use Supriad® if you have acne, rosacea, ulcers, atrophic skin disease or perioral dermatitis.

Your doctor will identify these conditions for you.

Do not use Supriad®

- after the expiry date printed on the pack OR
- if the packaging is torn, doesn't look quite right or shows signs of tampering.

If the Supriad® packaging is damaged or it is past the expiry date, return it to your pharmacist for disposal.

If you have not told your doctor about any of the above, tell him/her before you start using Supriad®.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have a known allergy to Supriad® or any ingredients listed at the end of this leaflet.

Tell your doctor if you

- are pregnant or plan to become pregnant
- · are breast-feeding
- · plan to breastfeed.

Your doctor can discuss with you the risks and benefits of using Supriad®.

Supriad® should be used only on the skin. Avoid getting Supriad® in your eyes. Do not put Supriad® in your mouth or come in contact with deep open wounds or mucous membranes. Do not swallow Supriad®.

Taking other medicines

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Supriad®.

How to use Supriad®

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How to use Supriad® preparations

 Supriad® ointment, fatty ointment and cream

Apply thinly to the affected area of skin.

· Supriad® lotion

Apply thinly to the affected area of skin and gently rub in.

When to use it

· Treatment of eczema

Use Supriad® once a day to treat the affected skin.

· Treatment of psoriasis

Use Supriad® ointment, fatty ointment or cream once or twice a day on the patches of psoriasis.

How long to use it

Usually, treatment with Supriad® is for up to 12 (twelve) weeks in adults and 4 (four) weeks in children.

Treatment with Supriad® should be for the shortest possible time period, and minimised to only on affected area. This is particulary important when using Supriad® under bandages.

This is particularly important when treating large areas, and in children.

Excessive application of topical corticosteroids to large areas of the body for prolonged periods of time can increase the risk of side effects. Discuss this with your doctor.

If you forget to use it

If you forget to use Supriad®, use it as soon as you remember. Then go on as before.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

If you use too much or use it other than directed (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much or swallowed some of this medicine. Do this even if there are no signs of discomfort or poisoning.

If you use too much Supriad® or use it for a long time, you may notice the following in the treated area:

- · your skin becomes thinner
- pink/purple stretch marks appear
- · a network of tiny blood vessels appears.

Stop using Supriad® if you have these symptoms and tell your doctor.

These symptoms usually disappear about two weeks after you stop using Supriad®.

While you are using Supriad®

Things you must do

Stop using Supriad® if you develop a skin allergy.

Tell your doctor if your skin becomes very dry when you use Supriad® cream or lotion. Your doctor may prescribe Supriad® ointment or fatty ointment instead.

If your eczema or psoriasis is infected, you must

- use specific anti-infection treatments prescribed by your doctor
- Stop using Supriad® if the infection spreads.

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Supriad®.

If you become pregnant while using Supriad®, tell your doctor immediately.

Things you must not do

Do not use Supriad® to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as

See also the section with the heading **Before** you use Supriad®.

Side effects

As with all medicines, Supriad® can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist:

- if you have any unpleasant effects while you are using Supriad® or
- if you notice any of the following and they worry you:
 - itching
 - burning
 - redness

The above list includes the more common side effects.

The following list includes side effects that are rare:

- · thinning of the skin
- the appearance of fine blood vessels on the skin surface
- stretch marks
- acne
- infection of hair follicles
- · excessive unwanted hair growth
- redness and irritation around the mouth (perioral dermatitis)
- · skin discolouration
- · allergic skin reactions.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using Supriad®

Keep Supriad® in its pack until required.

Storage

Keep your Supriad® ointment or cream in a cool dry place where the temperature stays below 25°C.

Keep your Supriad® fatty ointment or lotion in a cool dry place where the temperature stays below 30°C.

Do not store Supriad® or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Supriad® where children cannot reach it.

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

Do not use Supriad® after the expiry date on the pack.

Disposal

If your doctor tells you to stop using Supriad® or the expiry date has passed, ask your pharmacist what to do with any Supriad® that is left over.

Product description

What Supriad® formulations looks like

Supriad® ointment is a white to yellowish, opaque ointment, with a firm consistency.

Supriad® fatty ointment is a white to yellowish, semi-clear ointment, which is greasier than Supriad® ointment.

Supriad® **cream** is a white cream, lighter in consistency than the ointments, and less greasy.

Supriad® lotion is a white lotion, more fluid than the cream.

Ingredients

Supriad® ointment contains 1 mg of methylprednisolone aceponate per gram of ointment as the active ingredient. It also contains

- · white beeswax
- heavy liquid paraffin
- · white soft paraffin
- Dehymuls E
- · purified water

Supriad® fatty ointment contains 1 mg of methylprednisolone aceponate per gram of fatty ointment as the active ingredient. It also contains

- · heavy liquid paraffin
- · white soft paraffin
- · microcrystalline wax
- · hydrogenated castor oil.

Supriad® cream contains 1 mg of methylprednisolone aceponate per gram of cream as the active ingredient. It also contains

- decvl oleate
- · glyceryl monostearate
- · cetostearyl alcohol
- hard fat
- · Softisan 378
- PEG-40 stearate
- · glyceryl 85%
- butylated hydroxytoluene
- · benzyl alcohol
- · disodium edetate
- · purified water

Supriad® lotion contains 1 mg of methylprednisolone aceponate per gram of lotion as the active ingredient. It also contains

- medium chain trigylcerides
- · caprylic/capric/stearic triglycerides
- steareth-2

- · steareth-21
- · benzyl alcohol
- disodium edetate
- · glycerol
- purified water

Supriad® does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

The Australian Registration Numbers are Supriad® ointment AUST R 408456 Supriad® fatty ointment: AUST R 408457 Supriad® cream: AUST R 408455 Supriad® lotion: AUST R 408458

This is not all the information available on Supriad®. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Sponsor

Supriad® is sponsored in Australia by:

LEO Pharma Pty Ltd Brisbane, QLD Australia Australia

Toll Free No. 1800 991 778

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Toll Free No: 1800 195 055

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