NEW ZEALAND CONSUMER MEDICINE INFORMATION

BETA SCALP APPLICATION
Betamethasone valerate scalp lotion 0.1% w/w

What is in this leaflet

This leaflet answers some common questions about BETA SCALP APPLICATION.

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 BETA SCALP APPLICATION against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What BETA SCALP APPLICATION is used for and how it works

Your BETA SCALP APPLICATION contains the active ingredient betamethasone valerate. It belongs to a group of medicines known as topical corticosteroids. “Topical” means that they are applied onto the skin. Topical corticosteroids are used to help reduce the inflammation that causes the redness and itchiness in a variety of conditions (they are not ‘anabolic’ steroids which are sometimes misused by athletes).

BETA SCALP APPLICATION is used to treat conditions of the scalp, such as psoriasis and the inflammation associated with severe dandruff.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

BETA SCALP APPLICATION is available only with a prescription from your doctor.

There is no evidence that BETA SCALP APPLICATION is addictive.

Before you use BETA SCALP APPLICATION

When you must not use it:

Do not use BETA SCALP APPLICATION if you have an allergy to:

- any medicine containing betamethasone valerate
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include unusual reddening of the face, skin rash or hives, itching on the skin, short of breath, wheezing or finding it difficult to breath, swelling of the face, lips, tongue or other parts of the body.

Do not use BETA SCALP APPLICATION if you have an infection on your scalp.

Do not use BETA SCALP APPLICATION on children under the age of one year.

Safety and effectiveness on children younger than one year old have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Taking other medicines

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

Some medicines and BETA SCALP APPLICATION may interfere with each other. These include:

- ritonavir (a medicine used for the treatment of HIV)
- itraconazole (a medicine for the treatment of fungal infections).

These medicines may be affected by BETA SCALP APPLICATION or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.
**How to use BETA SCALP APPLICATION**

**How much to apply**
Your doctor will tell you how much BETA SCALP APPLICATION you need to apply each day. It is important that you apply BETA SCALP APPLICATION only as directed by your doctor.

**Do not use more than the recommended amount.**
Applying more than this may allow the active ingredient in this medication to pass through the scalp and into the blood stream. This could affect other parts of the body and may result in unwanted side effects.

For adults, BETA SCALP APPLICATION is usually applied to the scalp twice a day (once in the morning and once at night).

Your doctor may tell you to apply the scalp application differently to this. If so, it is important you follow their instructions.

When applying the application to your scalp, be careful that you do not let any run into your eyes.

**How long to apply it**
Your doctor will advise you how long to use BETA SCALP APPLICATION.

**Do not use BETA SCALP APPLICATION for any longer than your doctor has prescribed.**
Using this type of medicine for a long time may affect the normal production of steroids in your body and be harmful to your health.

Duration of treatment will depend on your condition and can vary between a few days to a longer period of time. If your scalp condition does not clear within a few weeks, tell your doctor.

Use on children should be limited to 5 days and dressing or bandages should not be used on children where the scalp application is applied.

**If you forget to apply it**
If you forget to use BETA SCALP APPLICATION apply it as soon as you remember then continue as before.

Do not apply extra BETA SCALP APPLICATION to make up for a missed dose.

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

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

**If you use too much (overdose)**
Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have accidently swallowed BETA SCALP APPLICATION; or if you or anyone else may have used too much BETA SCALP APPLICATION. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

**While you are using BETA SCALP APPLICATION**

**Things you must do**
Tell your doctor if, for any reason, you have not used your medicine exactly as directed. Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using BETA SCALP APPLICATION.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are going to have any blood tests, tell your doctor that you are using BETA SCALP APPLICATION.

Visit your doctor regularly so they can check on your progress, especially if your doctor has prescribed BETA SCALP APPLICATION for psoriasis.

**Things you must not do**
Do not use BETA SCALP APPLICATION on children under 1 year of age.

Do not use BETA SCALP APPLICATION to treat any other complaints or skin conditions unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not stop using your medicine without checking with your doctor.

If you use BETA SCALP APPLICATION regularly make sure you talk to your doctor before you stop using it.

Do not allow the BETA SCALP APPLICATION to run into your eyes.

If the application does accidentally enter your eyes, rinse your eye(s) thoroughly with water. Do not touch your eyes until you have washed your hands.

**Things to be careful of**
Only use an airtight dressing over this medicine if your doctor has told you to.

If you are applying BETA SCALP APPLICATION under an airtight dressing, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.

BETA SCALP APPLICATION is flammable so keep it away from fire.

Avoid smoking whilst applying it to the scalp and do not dry your hair with a hairdryer after applying BETA SCALP APPLICATION.
**Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using BETA SCALP APPLICATION. This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of possible 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 notice any of the following and they worry you:**
- skin rash
- hot burning sensation
- itching.

**Tell your doctor as soon as possible if you notice any of the following:**
- increased hair growth
- thinning of the skin and appearance of stretch marks
- changes to the colour of your skin
- appearance of blood vessels under the surface of your skin
- blurred vision.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:
- if your skin condition gets worse or your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection or need other treatment
- wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.
- The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Applying BETA SCALP APPLICATION for a long period of time, or covering the treated area with an airtight dressing may cause the following symptoms:**
- increased weight
- moon face / rounding of the face
- obesity
- skin thinning, this may cause stretch marks
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- increased body hair
- hair loss / lack of hair growth / damaged looking hair.

**Other very rare skin reactions that may occur are:**
- allergic reaction at the site of application
- worsening of condition
- irritation at the site of application
- redness
- rash or hives
- skin infection
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

**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.**

**Some very rare side effects can only be found when your doctor does blood tests or a medical examination:**
- decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- a weakening of the bones through gradual loss of mineral (osteoporosis).

**Additional tests may be needed after your medical examination to confirm if you have this condition.**

**After using BETA SCALP APPLICATION**

**Storage**

Keep your BETA SCALP APPLICATION in the container until it is time to use it.

Keep your BETA SCALP APPLICATION in a cool dry place where the temperature stays below 25°C. Avoid exposure to heat, light and moisture.

Do not store BETA SCALP APPLICATION, 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 it 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.

**Disposal**

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

**Product description**

**What it looks like**

BETA SCALP APPLICATION is an almost clear, colourless liquid.

**Ingredients**

BETA SCALP APPLICATION contains 0.1% w/w of betamethasone valerate as the active ingredient.

BETA SCALP APPLICATION also contains:
- isopropyl alcohol
- sodium hydroxide
• carbomer
• purified water.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
P O Box 11183,
Ellerslie,
AUCKLAND.

Telephone: (09) 579 2792

Date of information

15 May 2018 (Based on datasheet dated 9 May 2018)