

CLOBEX[®] SHAMPOO

Clobetasol propionate (0.05% w/w)

What is in this leaflet

1. What Clobex[®] Shampoo is used for
2. How Clobex[®] Shampoo works
3. Before you use Clobex[®] Shampoo
4. How to use Clobex[®] Shampoo
5. While you are using it
6. Side Effects
7. Storage and Disposal of Clobex[®] Shampoo
8. Product Description
9. Manufacturer and Product registration holder
10. Date of revision

What Clobex[®] Shampoo is used for
Clobex[®] Shampoo is used in adult to treat moderate to severe scalp psoriasis.

How Clobex[®] Shampoo works

Clobex[®] Shampoo contains clobetasol propionate which reduces the swelling, itching and redness. This medication is a very strong corticosteroid.

Before you use Clobex[®] Shampoo

- When you must not use it

Do not use Clobex[®] Shampoo if you are allergic to any of its ingredients, or any other corticosteroids. Clobex Shampoo is not recommended for use by people under 18 years of age.

- Before you start to use it

Tell your doctor:

- If you are pregnant, think you are pregnant. Talk with your doctor before using Clobex[®] Shampoo or if you are already using Clobex[®] Shampoo. It is not known if Clobex[®] Shampoo can harm your unborn baby.
- If you are breastfeeding. It is not known if Clobex[®] Shampoo passes into your milk, and if it can harm your baby. Clobex[®] Shampoo should be used cautiously during pregnancy and breastfeeding only if the potential benefit justifies the potential risk to the baby.
- If you think you have an infection on your scalp. You may need another medicine to treat the

scalp infection before you use Clobex[®] Shampoo.

Manifestations of Cushing's syndrome, high blood sugar level, and presence of sugar in the urine can also be produced in some people by systemic absorption of topical corticosteroids while on treatment.

Conditions which increase systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings or use on occluded areas.

If adrenal gland suppression is noted, your doctor may withdraw the medicine, to reduce the frequency of application, or to substitute a less potent steroid.

Children may be more susceptible to systemic toxicity due to their larger skin surface to body mass ratios.

If irritation develops, Clobex[®] Shampoo should be discontinued and doctor may prescribe other medications.

- Taking other medicines

Tell your doctor about all the other medicines and skin products you use, including prescription and non-prescription medicines, vitamins, herbal supplements, and cosmetics. Some medicines and products can cause serious side effects if used while you are using Clobex[®] Shampoo.

How to use Clobex[®] Shampoo

- How much to use

- Use Clobex[®] Shampoo exactly as prescribed by your doctor. Clobex[®] Shampoo is for use on your scalp only.
- Apply Clobex[®] Shampoo on affected areas of the scalp once a day in a thin film or as directed by your doctor. Use only enough to cover the affected areas of your scalp.
- Do not wet your hair before using Clobex[®] Shampoo. Move the hair

away from the scalp so that one of the affected areas is exposed. Apply a small amount of the shampoo directly onto the affected area by gently squeezing the bottle. Gently, rub Clobex[®] Shampoo into the affected area. Massage gently and repeat for other affected areas on your scalp.

- Leave Clobex[®] Shampoo in place for 15 minutes before adding water, lathering and rinsing hair and scalp completely. No other shampoos are necessary. However, you can use a non-medicated shampoo on your hair after using Clobex[®] Shampoo if you want to.

- When to use it

Use as prescribed by doctor.

- How long to use it

- Apply Clobex[®] Shampoo on affected areas of your scalp one time each day.
- You should not use Clobex[®] Shampoo any longer than 4 weeks (28 days) in a row for moderate to severe scalp psoriasis.
- Treatment should be limited to 4 consecutive weeks and should be discontinued when control is achieved. If complete disease control is not achieved after 4 weeks of treatment with Clobex[®] Shampoo, consult your doctor.

- If you forget to use it

If you forget to apply Clobex[®] Shampoo at the scheduled time, use it as soon as you remember, and then go back to your regular schedule. If you remembered at the time of your next application, apply only one dose and continue with your regular schedule. If you miss several doses, tell your doctor.

- If you use too much (overdose)

Clobex[®] Shampoo can pass through your skin, too much of Clobex[®] Shampoo passing through your skin can suppress your adrenal glands.

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While you are using it

- Things you must do

- Wash your hands after applying Clobex[®] Shampoo. Wash any other parts of your body that came into contact with Clobex[®] Shampoo such as your neck and shoulders.
- You should report any signs of local or systemic adverse reactions to your doctor.
- You should inform your doctor that you are using Clobex[®] Shampoo if surgery is contemplated.

- Things you must not do

Do not do the following while using Clobex[®] Shampoo:

- Do not use Clobex[®] Shampoo for any disorder other than that for which it was prescribed.
- Do not use Clobex[®] Shampoo on your lips or in or near your eyes because this might cause side effects. If you do, use a lot of water to rinse the Clobex[®] Shampoo off your face, lips or out of your eyes. If your eyes keep stinging after rinsing them well with water, contact your doctor right away.
- Do not use Clobex[®] Shampoo with occlusive dressings unless directed by your doctor.
- Do not apply Clobex[®] Shampoo to your face, groin or armpits.
- Do not get Clobex[®] Shampoo in your mouth. If you or your child accidentally swallows Clobex[®] Shampoo, call your Poison Control center or local emergency room right away.
- Do not cover your head with a shower or bathing cap while Clobex[®] Shampoo is on your scalp.
- Do not use more than 50ml (1.75 fluid ounces) of Clobex[®] Shampoo per week.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the medicine makes you feel sick, dizzy or tired, or give you a headache, do not drive or use

machines and contact your doctor immediately.

Side effects

All medicines may cause side effects, but many people have no, or minor, side effects.

The side effects with Clobex[®] Shampoo include burning or itching at the site of application. Other possible side effects include thinning of the skin and widening of small blood vessels in the skin.

Check with your doctor if any of the side effects persist or become bothersome.

Clobex[®] Shampoo can pass through your skin. Too much Clobex[®] Shampoo passing through your skin can suppress your adrenal gland. This may happen if you use too much Clobex[®] Shampoo or if you use it for too long, but it can happen with correct use.

If your adrenal glands are suppressed, they may not start working right away after you stop using Clobex[®] Shampoo. Suppressing of the adrenal glands can cause nausea, vomiting, fever, low blood pressure and even death because your body cannot adequately respond to stress or illness.

Your doctor may do special blood and urine tests to check your adrenal gland function while you are using Clobex[®] Shampoo.

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 portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Clobex[®] Shampoo

- Storage

- Keep the bottle tightly closed at all times.
- Store at controlled room temperature 68°F to 77°F

(20°C-25°C)

- Do not use Clobex[®] Shampoo after the expiration date shown on bottle. Keep Clobex[®] Shampoo and all medicines out of reach of children.

- Disposal

Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Clobex[®] Shampoo is a translucent, colorless to pale yellow viscous liquid with alcoholic odour.

- Ingredients

- Active ingredient
Clobetasol propionate

- Inactive ingredients:
Alcohol, Citric Acid, Coco-Betaine, Polyquaternium-10, Purified Water, Sodium Citrate And Sodium Laureth Sulfate.

- MAL number:

MAL06051300AZ

Manufacturer

Laboratoires Galderma
Z.I. de Montdesir
74540 Alby-Sur-Cheran
France.

Product Registration Holder

Zuellig Pharma Sdn Bhd
No 15, Persiaran Pasak Bumi,
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Selangor, 40150 Selangor.

Date of revision

17/02/2016

Serial Number:

BPFK(R4/1)101215/00491