

DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akom's Customer Service department at 800.932.5676.

Clobetasol Propionate Shampoo, 0.05%

PATIENT INFORMATION

Clobetasol Propionate Shampoo, 0.05% (kloe bay' ta sol proe' pee oh nate)

Important: For use on the scalp only. Do not get Clobetasol Propionate Shampoo near or in your eyes, mouth or vagina.

Read the Patient Information that comes with Clobetasol Propionate Shampoo before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is Clobetasol Propionate Shampoo?

- Clobetasol Propionate Shampoo is a prescription corticosteroid medicine used to treat adults with moderate to severe forms of scalp psoriasis. Clobetasol Propionate Shampoo is for use on the scalp only (topical).
- Clobetasol Propionate Shampoo should be used for the shortest amount of time needed to treat your scalp psoriasis.
- You should not use Clobetasol Propionate Shampoo for longer than 4 weeks in a row.
- You should not use more than 50 mL (1.75 fluid ounces) of Clobetasol Propionate Shampoo in one week.

You should not use Clobetasol Propionate Shampoo:

- on your face, underarms (armpits) or groin areas. Avoid getting Clobetasol Propionate Shampoo in your eyes or on your lips.

Clobetasol Propionate Shampoo should not be used in children under 18 years of age.

What should I tell my doctor before using Clobetasol Propionate Shampoo?

Before you use Clobetasol Propionate Shampoo, tell your doctor if you:

- have a scalp infection. You may need medicine to treat the scalp infection before you use Clobetasol Propionate Shampoo.
- have any open sores or cuts on your scalp
- plan to have surgery
- have acne vulgaris, rosacea, or a rash around your mouth (perioral dermatitis)
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Clobetasol Propionate Shampoo can harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if Clobetasol Propionate Shampoo passes into your breast milk.
- Talk to your doctor about the best way to feed your baby if you use Clobetasol Propionate Shampoo.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take other corticosteroid medicines by mouth or use other products on your skin that contain corticosteroids. You should not use other products that contain corticosteroids while you are using Clobetasol Propionate Shampoo. Ask your doctor or pharmacist if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist if you get a new medicine.

How should I use Clobetasol Propionate Shampoo?

- Use Clobetasol Propionate Shampoo exactly as your doctor tells you to use it.
- Your doctor should tell you how much Clobetasol Propionate Shampoo to use and where to apply it.
- Clobetasol Propionate Shampoo is for use on your scalp only (topical).
- Apply Clobetasol Propionate Shampoo on affected areas of your scalp one time each day.
- Use only enough Clobetasol Propionate Shampoo to cover the affected areas of your scalp.
- **Do not use Clobetasol Propionate Shampoo on your face, groin, or underarms. Avoid getting Clobetasol Propionate Shampoo in your eyes or on your lips.**
- **Do not wet your hair before using Clobetasol Propionate Shampoo.**
- **If Clobetasol Propionate Shampoo gets on any part of your body other than your scalp, rinse the area well with water.**
- **You should not bandage or cover your head with a shower cap, bathing cap, or a towel**, while Clobetasol Propionate Shampoo is on your scalp, unless your doctor tells you to.
- Tell your doctor if your scalp condition is not getting better after 4 weeks of using Clobetasol Propionate Shampoo. You should not use Clobetasol Propionate Shampoo for more than 4 weeks unless your doctor tells you to.

See the "Instructions for Use" at the end of the Patient Information for detailed information about the right way to use Clobetasol Propionate Shampoo.

What are the possible side effects of Clobetasol Propionate Shampoo?

Clobetasol Propionate Shampoo can pass through your skin. Too much Clobetasol Propionate Shampoo passing through your skin can cause your adrenal glands to stop working. Your doctor may do blood tests to check how well your adrenal glands are working.

The most common side effects of Clobetasol Propionate Shampoo include:

- burning or stinging at the site of application
- itching
- swelling

- inflamed hair follicle
- acne
- dry, itchy and reddened skin
- hair loss
- rash or hives
- thinning of the skin
- widening of small blood vessels in the skin

If you go to another doctor for illness, injury or surgery, tell that doctor that you are using Clobetasol Propionate Shampoo.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Clobetasol Propionate Shampoo. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010.

How should I store Clobetasol Propionate Shampoo?

- Store Clobetasol Propionate Shampoo at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the Clobetasol Propionate Shampoo bottle tightly closed.

Keep Clobetasol Propionate Shampoo and all medicines out of the reach of children.

General information about Clobetasol Propionate Shampoo

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Clobetasol Propionate Shampoo for a condition for which it was not prescribed. Do not give Clobetasol Propionate Shampoo to other people, even if they have the same symptoms that you have. It may harm them. This Patient Information leaflet summarizes the most important information about Clobetasol Propionate Shampoo. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Clobetasol Propionate Shampoo that is written for health professionals.

What are the ingredients in Clobetasol Propionate Shampoo?

Active ingredient: clobetasol propionate

Inactive ingredients (shampoo base): alcohol, citric acid, coco-betaine, polyquaternium-10, purified water, sodium citrate and sodium laureth sulfate.

Manufactured by:
Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701

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Instructions for Use
Clobetasol Propionate Shampoo
(kloe bay' ta sol proe' pee oh nate)

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How to apply Clobetasol Propionate Shampoo to your scalp:

Your hair should be dry when you apply Clobetasol Propionate Shampoo to your scalp.

Do not get Clobetasol Propionate Shampoo on your face, in your eyes or on your lips. If Clobetasol Propionate Shampoo does get on these areas, rinse well with water.

Step 1: To apply Clobetasol Propionate Shampoo to your scalp, part your hair at the area where it is to be applied.

Step 2: Hold the bottle of Clobetasol Propionate Shampoo over the affected area. Gently squeeze the bottle and apply a small amount of shampoo to the affected area.

Step 3: Gently rub Clobetasol Propionate Shampoo into the affected area so that only the affected area is covered with a thin, even layer of Clobetasol Propionate Shampoo.

Step 4: Repeat Steps 1 through 3 to apply Clobetasol Propionate Shampoo to other affected areas on your scalp as instructed by your doctor.

Step 5: Wash your hands after applying Clobetasol Propionate Shampoo.

Step 6: Leave Clobetasol Propionate Shampoo on your scalp for 15 minutes. You should not bandage or cover your head with a shower cap, bathing cap, or a towel while Clobetasol Propionate Shampoo is on your scalp, unless your doctor tells you to.

Step 7: After 15 minutes have passed, wet your hair with water. Lather and rinse your hair and scalp completely. Rinse any other parts of your body that come into contact with Clobetasol Propionate Shampoo, such as your hands, face, neck and shoulders.

No other shampoo is needed, but you may wash your hair with a non-medicated shampoo after using Clobetasol Propionate Shampoo.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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