

Summary of VANOS Cream® Safety Information

- VANOS® Cream is a corticosteroid (steroid hormone) approved to relieve the inflammation and itching caused by certain skin conditions that respond to treatment with corticosteroids in patients 12 years of age or older.
- Treatment should not exceed two weeks or 60 grams per week, because the safety of using VANOS® Cream beyond two weeks has not been established and because it may reduce levels of hormones that regulate your body's immune system and energy levels (HPA-axis suppression). Do not use more than half of the 120-gram tube in a week.
- You should stop using VANOS® Cream when your skin condition is under control. If you see no improvement in two weeks, contact your doctor.
- After you stop using VANOS® Cream, your adrenal gland may temporarily be unable to make enough of the hormones your body needs to adapt to stress (glucocorticosteroid insufficiency). HPA-axis suppression occurred in two out of 18 adult patients with psoriasis treated twice daily for two weeks and in one out of 31 adult patients with atopic dermatitis treated once daily for two weeks. How often HPA-axis suppression occurs in psoriasis patients who are less than 18 years of age has not been determined. Because children have more skin compared to their body weight, they have a greater risk than adults of HPA-axis suppression and Cushing's syndrome (a fatty hump between your shoulders, a rounded face, and pink or purple stretch marks) when they apply corticosteroids (steroid hormones) to the skin.
- If irritation develops, stop using VANOS® Cream and call your doctor.
- VANOS® Cream should not be used on the face, groin, or underarms; or for treatment of rosacea (flushed skin and pimples) or rash around the mouth.
- The safety and efficacy in patients younger than 12 years of age have not been established.
- The most commonly reported adverse events were headache, burning at the application site, inflammation of the nasal passages and upper throat, and nasal congestion.