

Patient Education - Tretinoin 0.04%, Dapsone 6%, Kojic Acid 3%, Clindamycin 1%, Spironolactone 5%, Niacinamide 5% Topical Gel

Hillcrest Pharmacy 781 E FT Union Blvd Midvale, UT 84047 – Direct 385-900-1400, Toll Free 1-855-499-2556

Patient Education Insert

-Apply medication to affected area as prescribed

This medication was compounded by a pharmacy per prescriber request. For external use only. Wash hands before and after use unless the medication is for your hands. Store at room temperature (68 to 77 degrees Fahrenheit). Keep away from children and pets. Do not flush unused medications or pour down a sink or drain. Do not swallow and avoid contact with eyes. Do not use more than your medical provider has instructed you to use. Do not use more often or for longer than you were instructed. Doing any of these may increase the chance of undesirable side effects.

The “Do not use after” date printed on the prescription label is generated using State & Federal compounding laws. Some preparations are made 1-3 days before the prescription is issued, in anticipation of expected demand. If you have any questions or concerns regarding this, please do not hesitate to call and speak to one of our pharmacists.

Do not use if an allergic reaction occurs due to any of the listed active ingredients on the prescription label. Signs of an allergic reaction may include rash hives itching shortness of breath wheezing cough swelling of face, lips, tongue or throat or any other signs.

Contact your medical provider or pharmacy if you have concerns about listed side effects or if you experience unexpected irritation. Notify your medical provider of any medical updates and of all drug changes including over-the-counter and herbal medications.

If you miss an application, apply as soon as you remember. If it is close to the next application, skip the missed application. Do not double applications.

We want to offer you the best service possible. In the event you have a concern or complaint please call the pharmacy at 385-900-1400.

MedWatch: The FDA Safety Information and Adverse Event Reporting Program
Website address: <https://www.fda.gov/Safety/MedWatch/default.htm>
Toll free number: 1-888-463-6332

Your medication contains the following active ingredients. Please review the following:

Tretinoin - Tretinoin is a form of vitamin A that helps the skin renew itself, is used to treat acne, to smooth rough facial skin, and to reduce the appearance of fine wrinkles and mottled skin discoloration.

Tretinoin topical may also be used for purposes not listed in this medication guide.

More frequently reported side effects include: exfoliation of skin, stinging of the skin, localized warm feeling, and mild erythema of skin.

Do not give tretinoin topical to a child without medical advice. Some brands of tretinoin topical are not approved for use in anyone under 18.

It is not known whether tretinoin topical will harm an unborn baby. Tell your doctor if you are pregnant.

It may not be safe to breast-feed a baby while you are using this medicine. Ask your doctor about any risks.

Wash your hands before and after applying tretinoin topical. Before applying, clean and dry the skin area to be treated. Applying tretinoin topical to wet skin may cause skin irritation.

Do not wash the treated area or apply other skin products for at least 1 hour after applying tretinoin topical.

Tretinoin topical should be used as part of a complete skin care program that includes avoiding sunlight and using an effective sunscreen and protective clothing.

Call your doctor at once if you have:

severe burning, stinging, or irritation of treated skin severe skin dryness or severe redness, swelling, blistering, peeling, or crusting.

Your skin may be more sensitive to weather extremes such as cold and wind while using tretinoin topical.

Common side effects may include: skin pain, redness, burning, itching, or irritation sore throat mild warmth or stinging where the medicine was applied or changes in color of treated skin.

Dapsone - an anti-infective medication.

Dapsone topical (for the skin) is used to treat acne & may also be used for purposes not listed in this medication guide.

To make sure dapsone topical is safe for you, tell your doctor if you have:

glucose 6-phosphate dehydrogenase (G6PD) deficiency a blood disorder called methemoglobinemia (abnormal red blood cells in your blood) or if you have ever had methemoglobinemia in the past.

It is not known whether dapsone topical will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

Dapsone topical can pass into breast milk and may harm a nursing baby. You should not breast-feed while using this medicine.

Get emergency medical help if you have signs of an allergic reaction: hives difficult breathing swelling of your face, lips, tongue, or throat.

Dapsone topical may cause methemoglobinemia (met-HEEM-oh glo-bin-EE-mee-a), a serious condition in which the amount of oxygen in your blood stream becomes dangerously low. Stop using this medicine and call your doctor at once if you notice a blue or gray appearance of your lips, fingernails, or the inside of your mouth.

Call your doctor at once if you have: Severe sore throat unusual thoughts or behavior a red blood cell disorder back pain, pale or yellowed skin, dark colored urine, fever, confusion or weakness pancreas problems severe pain in your upper stomach spreading to your back, nausea and vomiting, fast heart rate or severe skin reaction fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

Common side effects may include: Dry or peeling skin oily skin or redness where the medicine was applied.

Kojic Acid - Kojic acid is made from several different types of fungi which inhibits and prevents the formation of tyrosine, which is an amino acid that's needed to produce melanin. Melanin is the pigment that affects hair, skin, and eye color. Because it inhibits the production of melanin, kojic acid can have a lightening effect.

Contact dermatitis is the most common side effect of kojic acid. It can manifest itself as redness, irritation, itchiness, rashes, swollen skin, or pain and discomfort. Contact dermatitis is most common in those with sensitive skin.

Over time, long-term use of kojic acid may make your skin more susceptible to sunburn. Keep this in mind, and be particularly mindful of using sunscreen or wearing protective clothing. You should never use kojic acid on damaged or broken skin.

Clindamycin - Used to treat severe acne in adults and children who are at least 12 years old. Clindamycin topical may also be used for purposes not listed in this medication guide.

You should not use clindamycin topical if you are allergic to clindamycin or lincomycin, or if you have: inflammation of your intestines (also called enteritis) ulcerative colitis or if you have ever had severe diarrhea caused by antibiotic medicine.

Tell your doctor if you have ever had: eczema or other skin problems or an intestinal disorder.

It is not known whether this medicine will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

If you are breastfeeding, tell your doctor if you notice diaper rash, diarrhea, or signs of stomach pain in the nursing baby. If you apply clindamycin foam to your chest, avoid areas that may come into contact with the baby's mouth.

Stop using clindamycin topical and call your doctor at once if you have: severe redness, itching, or dryness of treated skin areas or severe stomach pain, diarrhea that is watery or bloody (even if it occurs months after your last dose).

Common side effects may include: burning, itching, dryness, peeling or redness of treated skin or oily skin.

Spirolactone- Oral spironolactone is a potassium-sparing diuretic primarily used for treating conditions such as high blood pressure and fluid retention. However, it has also been found to be effective in treating certain types of acne, particularly in adult women.

Spirolactone is an antiandrogen, which means it inhibits the effects of androgens (male hormones) in the body. Acne in women is often influenced by androgens, specifically dihydrotestosterone (DHT). DHT stimulates the oil glands in the skin, leading to increased sebum (oil) production, clogged pores, and the development of acne lesions.

By blocking the androgen receptors, spironolactone reduces the effects of androgens on the skin, resulting in decreased sebum production. This helps to unclog pores, reduce inflammation, and prevent the formation of new acne lesions. Spirolactone also has an anti-inflammatory effect, which can further contribute to its efficacy in treating acne.

It's important to note that spironolactone is typically prescribed for moderate to severe acne that is resistant to other treatments. It is often used as an off-label treatment, meaning it is not FDA-approved specifically for acne but has shown effectiveness in clinical practice

You should not use spironolactone if you are allergic to it, or if you have: Addison's disease (an adrenal gland disorder) high levels of potassium in your blood (hyperkalemia) if you are unable to urinate or if you are also taking eplerenone.

To make sure spironolactone is safe for you, tell your doctor if you have: an electrolyte imbalance (such as low levels of calcium, magnesium, or sodium in your blood) kidney disease liver disease or heart disease.

Pregnant women should not use spironolactone. Tell your doctor if you are pregnant or plan to become pregnant. Having congestive heart failure, cirrhosis, or uncontrolled high blood pressure during pregnancy may lead to medical problems in the mother or the baby.

It may not be safe to breastfeed while using spironolactone. Ask your doctor about any risk.

Call your doctor at once if you have: a light-headed feeling, like you might pass out little or no urination high potassium level - nausea, weakness, tingly feeling, chest pain, irregular heartbeats, loss of movement signs of other electrolyte imbalances - increased thirst or urination, confusion, vomiting, muscle pain, slurred speech, severe weakness, numbness, loss of coordination, feeling unsteady.

Common spironolactone side effects may include: breast swelling or tenderness.

This is not a complete list of side effects and others may occur.

Niacinamide – Topical anti-inflammatory

When applied topically, niacinamide has been shown to have anti-inflammatory effects on the skin. It has been used to treat skin conditions like acne and rosacea, a facial skin disorder characterized by redness.

Possible side effects include: mild burning, itching, or redness.