

Patient Education - Spironolactone 5%, Azelaic Acid 12%, Niacinamide 2%, Tea Tree oil Topical Cream

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:

Spironolactone- Oral spironolactone is a potassium-sparing diuretic that prevents your body from absorbing too much salt and keeps your potassium levels from getting too low. It is used to treat heart failure, high blood pressure (hypertension), or hypokalemia (low potassium levels in the blood). Spironolactone also treats fluid retention (edema) in people with congestive heart failure, cirrhosis of the liver, or a kidney disorder called nephrotic syndrome. Spironolactone is also used to diagnose or treat a condition in which you have too much aldosterone in your body. Aldosterone is a hormone produced by your adrenal glands to help regulate the salt and water balance in your body. Acne has also been treated using spironolactone (off-label) with clinically significant results for many years.

The use of spironolactone topically is a relatively new approach to treating acne. The topical use has been shown to be effective in clinical trials, however the topical side effects are also not fully available. Topically applied medications are generally not absorbed into the bloodstream in significant amounts, however, please refer to oral use information below as a general guide for use, and please contact your physician or pharmacist with any unanswered or additional questions.

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.

Azelaic Acid - a naturally occurring acid. It helps the skin to renew itself more quickly and therefore reduces pimple and blackhead formation. It also helps to kill the bacteria that cause acne and rosacea.

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

Azelaic acid topical is not expected to harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment.

It is not known whether azelaic acid topical passes into breast milk or if it could harm a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

Stop using azelaic acid topical and call your doctor at once if you have:

severe burning, stinging, or warmth severe itching or tingling severe redness, dryness, peeling, or other irritation or changes in skin color.

Less serious side effects are more likely, and you may have none at all.

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.