Medication Guide

ACUNOL[®] Tablets

Read the Medication Guide that comes with **Acunol**[®] before you start taking it and each time you get a prescription. 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 ACUNOL[®]?

Acunol[®] is a biochemical homeopathic medication taken by mouth to treat mild to moderate acne vulgaris, acne rosacea, perioral dermatitis and folliculitis. It has been found to work well with a variety of combination acne therapies.

Who should not take ACUNOL®?

- **Do not** take Acunol[®] if you are pregnant, plan to become pregnant or become pregnant during Acunol[®] treatment.
- Although there are no known contraindications, consult with your doctor prior to taking Acunol[®] if you are allergic to any of the ingredients in Acunol[®]. See the end of this Medication Guide for a complete list of ingredients in Acunol[®].

What should I tell my doctor before taking Acunol®?

Tell your doctor if you have a history of kidney disease. The doctor will adjust the dosage.

Tell your doctor if you are pregnant.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. Especially tell your doctor if you take Tetracycline or Levofloxacin or a different Quinolone antibiotic, as your doctor will instruct you to allow at least two hours after taking Acunol[®] to take these other medications.

How should I take Acunol®?

You must take Acunol[®] exactly as prescribed by your doctor. It is important to take orally at the beginning of the day on an empty stomach and at the end of the day before bed; take nothing but water for one hour afterwards to avoid interference with Acunol[®] absorption.

The amount of Acunol[®] you take has been specially chosen for you. It is based upon your body weight.

Acunol[®] may be swallowed whole, chewed or dissolved in the mouth.

If you miss a dose, just skip that dose. Do not take two doses at the same time.

If you take too much Acunol® or overdose, call your doctor or poison control center right away.

What are the possible side effects of Acunol®?

Acunol[®] contains low doses of active ingredients. Therefore, there are minimal known side effects.

Tell your doctor if you have a history of contact sensitivity to nickel (common in metal) or if there is a history of vesicular hand eczema (dyshidrotic, pomphylos). Nickel sensitivity may be confirmed by a positive nickel patch test by your doctor. If you have nickel sensitivity, your doctor will prescribe a very low dose to start and then slowly increase your dosage over a 5 week period.

If you develop a rash, discontinue Acunol[®] use and consult with your doctor.

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 Plymouth Pharmaceuticals, the Manufacturer of Acunol[®] at 1-952-903-7621.

How should I store Acunol[®]?

- Store Acunol[®] at room temperature, 68 to 77 Fahrenheit. Protect from light.
- Keep Acunol[®] and all medicines out of the reach of children.

General Information about Acunol®

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use Acunol[®] for a condition for which it was not prescribed. Do not give Acunol[®] to other people, even if they have the same symptoms that you have.

This Medication Guide summarizes the most important information about Acunol[®]. If you would like more information, talk with your doctor.

You can ask your doctor or pharmacist for information about Acunol[®] that is written for health care professionals. You can also visit: <u>www.plymouthpharmaceuticals.com</u>.

What are the ingredients in Acunol[®]?

Active Ingredients: Potassium Bromide (Kali Bromatum 1X), Sodium Bromide (Natrum Bromatum 1X), Zinc Sulphate (Zincum Sulphuricum 1X), Sulphur 1X and Nickel Sulphate (Niccolum Sulphuricum 1X). These drug ingredients are listed in the Homeopathic Pharmacopoeia of the United States (HPUS).

Inactive Ingredients: Lactose, Magnesium Stearate, Copper (II) Oxide.

Acunol[®] is a registered trademark of Plymouth Healthcare Products LLC. 6521 Davis Industrial Parkway Solon, Oh 44139 Email: <u>plymouthpharm@gmail.com</u> Toll Free: 1-952-903-7621 www.plymouthpharmaceuticals.com