

17.5 FDA-Approved Patient Labeling

PATIENT INFORMATION

ACANYA® (*AH-CAN'-YAH*) Gel

(clindamycin phosphate 1.2% and benzoyl peroxide 2.5%)

IMPORTANT: For use on skin only (topical use). Do not get ACANYA Gel in your mouth, eyes, or vagina, or on your lips.

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

What is ACANYA Gel?

ACANYA Gel is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years and older. ACANYA Gel contains clindamycin phosphate and benzoyl peroxide.

It is not known if ACANYA Gel is safe and effective for use longer than 12 weeks.

It is not known if ACANYA Gel is safe and effective in children under 12 years of age.

Who should not use ACANYA Gel?

Do not use ACANYA Gel if you have:

- Crohn's disease
- ulcerative colitis
- had inflammation of the colon (colitis), or severe diarrhea with past antibiotic use

Talk with your doctor if you are not sure if you have one of these conditions.

What should I tell my doctor before using ACANYA Gel?

Before using ACANYA Gel, tell your doctor about all of your medical conditions, including if you:

- **have any allergies.**
- **are pregnant or planning to become pregnant.** It is not known if ACANYA Gel will harm your unborn baby.
- **are breast-feeding or plan to breast-feed.** It is not known if ACANYA Gel passes into your breast milk. One of the medicines in ACANYA Gel contains clindamycin. Clindamycin when taken by mouth or by injection has been reported to appear in breast milk. You and your doctor should decide whether you will use ACANYA Gel while breast-feeding.

Tell your doctor about all the medicines and skin products you use. Especially tell your doctor if you will have surgery with general anesthesia. One of the medicines in ACANYA Gel (clindamycin) can affect how certain medicines work when used in general anesthesia.

- ACANYA Gel should not be used with products that contain erythromycin.
- Other skin and topical acne products may increase the irritation of your skin when used with ACANYA Gel.

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

How should I use ACANYA Gel?

- Use ACANYA Gel exactly as prescribed.
- Your doctor will tell you how long to use ACANYA Gel.
- Throw away (discard) any unused ACANYA Gel.

Instructions for applying ACANYA Gel

- Apply ACANYA Gel to your face one time each day as prescribed.
 1. Before you apply ACANYA Gel, wash your face gently with a mild soap, rinse with warm water, and pat your skin dry.
 2. To apply ACANYA Gel to your face, use your fingertip and take one pea-sized amount of ACANYA Gel from the jar. See Figure 1. One pea-sized amount of ACANYA Gel should be enough to cover your entire face.
 3. Dot the one pea-sized amount of ACANYA Gel onto six areas of your face (chin, left cheek, right cheek, nose, left forehead, right forehead). See Figure 2.
 4. After applying the ACANYA Gel this way, spread the gel over your face and gently rub it in. It is important to spread the gel over your whole face.
 5. Wash your hands with soap and water after applying ACANYA Gel.
 6. If your doctor tells you to put ACANYA Gel on other areas of your skin with acne, be sure to ask how much you should use.
 7. Do not get ACANYA Gel in your mouth, eyes, or nose, or on your lips. If this occurs, rinse the affected area with warm water and call your doctor right away if the area becomes very red, itchy, tender, or swollen.
 8. Do not get ACANYA Gel on cuts or open wounds.
 9. Do not use more ACANYA Gel than prescribed.

Figure 1

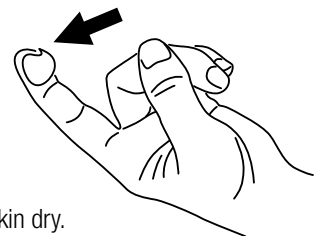
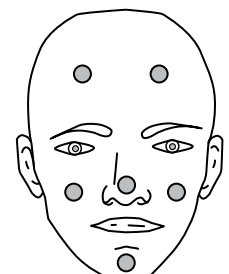


Figure 2



What should I avoid while using ACANYA Gel?

- Limit your time in sunlight. Avoid using tanning beds or sun lamps. If you have to be in sunlight, wear a wide-brimmed hat or other protective clothing, and a sunscreen with SPF 15 rating or higher. Your doctor can give you more information about why this is important.
- Do not wash your face more than 2 to 3 times a day. Washing your face too often or scrubbing it may make your acne worse.
- Avoid getting ACANYA Gel in your hair or on colored fabric. ACANYA Gel may bleach hair or colored fabric.

What are possible side effects with ACANYA Gel?

ACANYA Gel can cause serious side effects including:

- **Inflammation of the colon (colitis).** Stop using ACANYA Gel and call your doctor right away if you have severe watery diarrhea, or bloody diarrhea.

Common side effects with ACANYA Gel include:

- **Skin irritation.** Stop using ACANYA Gel and call your doctor if you have a skin rash or your skin becomes very red, itchy or swollen.

Talk to your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects with ACANYA Gel. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or CORIA Laboratories at 1-877-272-8808.

How should I store ACANYA Gel?

- Store ACANYA Gel at room temperature at or below 77°F (25°C).
- The expiration date is 2 months from the date you fill your prescription.
- Safely throw away expired ACANYA Gel.
- Do not freeze.
- Keep the jar tightly closed.

Keep ACANYA Gel and all medicines out of the reach of children.

General information about ACANYA Gel

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information leaflets. Do not use ACANYA Gel for a condition for which it was not prescribed. **Do not give ACANYA Gel to other people, even if they have the same condition you have. It may harm them.**

This leaflet summarizes the most important information about ACANYA Gel. If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information about ACANYA Gel that is written for healthcare professionals.

For more information about ACANYA Gel, call 1-877-272-8808 or go to www.AcanyaGel.com.

What are the ingredients in ACANYA Gel?

Active Ingredients: clindamycin phosphate 1.2% and benzoyl peroxide 2.5%

Inactive Ingredients: purified water, carbomer 980, propylene glycol, and potassium hydroxide

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U.S. Patents 5,733,886 and 6,117,843

Additional Patents Pending