PATIENT INFORMATION
Adapalene (a ‘dapa’ a ‘leen’) and Benzoyl Peroxide (ben’ zoe’ li per’ ox’ ide) Gel 0.1%/2.5%

Rx Only
Important: For use on the skin only (topical). Do not use adapalene and benzoyl peroxide gel on or in your mouth, eyes, or vagina.

Read this Patient Information leaflet about adapalene and benzoyl peroxide 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 treatment or your medical condition. If you have any questions about adapalene and benzoyl peroxide gel, talk with your doctor or pharmacist.

What is adapalene and benzoyl peroxide gel?
Adapalene and benzoyl peroxide gel is a prescription medicine for skin use only (topical) used to treat acne vulgaris in patients 9 years of age and older.

Acne vulgaris is a condition in which the skin has blackheads, whiteheads, and pimples. It is not known if adapalene and benzoyl peroxide gel is safe and effective in children younger than 9 years old.

What should I tell my doctor before using adapalene and benzoyl peroxide gel?
Before you use adapalene and benzoyl peroxide gel, tell your doctor if you:
• have other skin problems, including cuts or sunburn
• have any other medical conditions
• are pregnant or plan to become pregnant
• are breastfeeding or plan to breastfeed

It is not known if adapalene and benzoyl peroxide gel is safe and effective in children younger than 9 years old.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Adapalene and benzoyl peroxide gel with topical medicines that contain sulfer, resorcinol or salicylic acid may cause skin irritation.

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

How should I use adapalene and benzoyl peroxide gel?
• Use adapalene and benzoyl peroxide gel exactly as your doctor tells you to use it. Adapalene and benzoyl peroxide gel is for skin use only. Do not use adapalene and benzoyl peroxide gel in or on your mouth, eyes, or vagina.

• Apply adapalene and benzoyl peroxide gel 1 time a day.
• Do not use more adapalene and benzoyl peroxide gel than you need to cover the treatment area. Using too much adapalene and benzoyl peroxide gel or using it more than 1 time a day may increase your chance of skin irritation.

Applying adapalene and benzoyl peroxide gel:
• Wash the area where the gel will be applied with a mild cleanser and pat dry.

• Adapalene and benzoyl peroxide gel comes in a tube and a pump. If you have been prescribed:
  o Tube: Squeeze a small amount (about the size of a pea) of adapalene and benzoyl peroxide gel onto your fingertips and spread a thin layer over the affected area.
  o Pump: Depress the pump to dispense a small amount (about the size of a pea) of adapalene and benzoyl peroxide gel.

• Use adapalene and benzoyl peroxide gel for 12 weeks. Continue to use adapalene and benzoyl peroxide gel once daily until your skin improves and then you can use adapalene and benzoyl peroxide gel 2 times a week to maintain improvement.

Tell your doctor if you use any other medicine for acne
Adapalene and benzoyl peroxide gel may cause serious side effects. These include:

- **Heart problems:** Adapalene has caused changes in heart rhythm in lab studies. Although these changes have not been seen in clinical studies, this is a concern. If you have heart problems such as heart failure or heart block, tell your doctor before using adapalene and benzoyl peroxide gel.

- **Eye problems:** Adapalene and benzoyl peroxide gel may affect your eyes. If you have any eye problems, tell your doctor before using the gel.

- **Liver problems:** Adapalene and benzoyl peroxide gel may cause liver problems. If you have any liver problems, tell your doctor before using the gel.

- **Renal problems:** Adapalene and benzoyl peroxide gel may affect your kidneys. If you have any kidney problems, tell your doctor before using the gel.

- **Pregnancy**: Adapalene and benzoyl peroxide gel may cause birth defects. If you are pregnant or plan to become pregnant, do not use adapalene and benzoyl peroxide gel. Use birth control if you are a woman who can get pregnant.

- **Breastfeeding**: It is not known if adapalene and benzoyl peroxide gel passes into breast milk. If you are breastfeeding or plan to breastfeed, do not use adapalene and benzoyl peroxide gel.

- **Children and adolescents**: Adapalene and benzoyl peroxide gel have been studied in children and adolescents, but more studies are needed to determine whether they respond differently from younger subjects.

- **Other side effects**: Adapalene and benzoyl peroxide gel may cause other side effects. Tell your doctor if you have any side effect that bothers you or that does not go away.

- **Important information about adapalene and benzoyl peroxide gel**

  **Prescribing Information**: This Patient Information has been approved by the U.S. Food and Drug Administration. This Patient Information leaflet summarizes the most important information about adapalene and benzoyl peroxide gel. It does not list all the possible side effects of adapalene and benzoyl peroxide gel. For more information, ask your doctor or pharmacist. This Information is not a representation of U.S. prescribing information. For complete Prescribing Information, see full prescribing information at www.actavis.com.

  **Table of Clinical Efficacy of Adapalene and Benzoyl Peroxide Gel at Week 12**

<table>
<thead>
<tr>
<th>treated group</th>
<th>mean Absolute 15.4</th>
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<tbody>
<tr>
<td>Adapalene and benzoyl peroxide gel</td>
<td>20.2 (54.7%)</td>
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**16 NEW SUPPLEMENTATION AND HARMING**
Adapalene and benzoyl peroxide gel may be harmful if it is taken in very large doses or for a long time. If you take adapalene and benzoyl peroxide gel, never take more of it or take it for a longer time than your doctor told you to. Do not share your medicine with others. This is especially important for children, who may accidentally take too much of this medicine.

**Keep out of reach of children.**

**17 PATIENT COUNSELING INFORMATION**

- **What you should tell your healthcare provider**: Before you start taking adapalene and benzoyl peroxide gel, tell your healthcare provider about all your medical conditions, including:
  - Adapalene and benzoyl peroxide gel may affect many other medicines you use. This includes prescription and nonprescription medicines, vitamins, and dietary supplements. Do not use any other medicines without first talking to your healthcare provider.
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**Actavis**

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**Table 1. Clinical Efficacy of Adapalene and Benzoyl Peroxide Gel at Week 12**

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