Inflammatory lesions are more apparent; many comedones and papules.

**Baseline**

<table>
<thead>
<tr>
<th>N = 219 (%), N = 476</th>
<th>N = 1,104</th>
</tr>
</thead>
<tbody>
<tr>
<td>42.9%</td>
<td>34.0%</td>
</tr>
<tr>
<td>26 (2)</td>
<td>20.2%</td>
</tr>
</tbody>
</table>

What are the ingredients in VELTIN Gel?

**Active Ingredients:**

- Clindamycin

**Other Ingredients:**

- Alcohol 31.2% w/w
- Edetate disodium 0.1% w/w
- Propylene glycol 33.3% w/w
- Purified water

**Microbiology (12.4)**

The clindamycin-containing product is active against a wide range of aerobic and anaerobic Gram-positive organisms. It may also exhibit activity against certain Gram-negative bacteria, including some strains of **E. coli** and **P. aeruginosa**. The in vitro susceptibility of a bacterial isolate to clindamycin is primarily determined by the minimum inhibitory concentration (MIC) of clindamycin. The MIC values for clindamycin are generally lower than those for **erythromycin**. The clinical significance of this difference has not been determined.

**Clinical Studies (14)**

In a randomized, double-blind, controlled study, 1,649 subjects with mild to moderate acne were treated for 12 weeks. The subjects were randomized to VELTIN Gel, clindamycin gel, tretinoin gel, or vehicle gel. The primary endpoint was the clinician's global assessment (IGA) at Week 12. The efficacy results at Week 12 are presented in Table 3.

**Warnings and Precautions**

- **Contraindications**
  - VELTIN Gel should not be used in combination with erythromycin-containing products because of its clindamycin component.
- **Adverse Reactions**
  - The most common adverse reactions reported in clinical trials were application site pruritus, application site exfoliation, and erythema.
- **Geriatric Use**
  - No special precautions are required for the use of VELTIN Gel in the elderly population.
- **Pediatric Use**
  - VELTIN Gel is not recommended for use in children under 12 years of age.
- **Nursing Mothers**
  - Clindamycin is not excreted in human milk following use of VELTIN Gel.
- **General Information**
  - VELTIN Gel should not be used by individuals who are allergic to clindamycin or other penicillins. VELTIN Gel should be used with caution in individuals with a history of antibiotic-associated colitis.

**Nonclinical Toxicology**

Reproductive Toxicology

The potential for VELTIN Gel to cause impaired fertility was evaluated in Sprague Dawley rats. A single dose of VELTIN Gel administered on gestation days 6-10 resulted in a reduction in fertility rates and increased abortion rates. The recommended human dose is based on body surface area, and it has been estimated that a rat would have to be exposed to approximately 16 times the human recommended dose to achieve similar effects. The significance of these findings is unknown.

**Photosensitization**

The photocarcinogenic potential of the clindamycin tretinoin combination is unknown. The potential for VELTIN Gel to cause photodamage has not been evaluated.

**Mutagenicity and Carcinogenicity**

VELTIN Gel was negative for mutagenic potential when evaluated in an in vitro Ames test. The carcinogenic potential of clindamycin has not been evaluated in any animal species.

**Teratology**

A teratology study performed in Sprague Dawley rats treated topically with VELTIN Gel or 0.025% tretinoin gel at a dose of 2 mL/kg during gestation days 6-10 resulted in abnormalities consistent with retinoid effects. The abnormalities occurred at 16 times the recommended clinical dose based on body surface area comparison.

**Pharmacology**

**Pharmacokinetics**

The mean absolute reduction in baseline IGA score of 3.0 was 0.88 at Week 12. The mean absolute reduction in baseline IGA score for VELTIN Gel-treated subjects was 0.40 at Week 12. The mean absolute reduction in baseline IGA score for subjects treated with other treatments was 0.00 at Week 12. The mean absolute reduction in baseline IGA score for subjects treated with other treatments was 0.40 at Week 12.

**Adverse Reactions**

**Contraindications**

- Hypersensitivity to clindamycin or other penicillins.
- History of antibiotic-associated colitis.

**Warnings**

- This drug is contraindicated in patients with known sensitivity to clindamycin or other penicillins.
- Do not use VELTIN Gel for a condition for which it was not prescribed.

**Precautions**

- Use VELTIN Gel with caution in patients with a history of antibiotic-associated colitis.
- Use VELTIN Gel with caution in patients with a history of colitis.

**General Information**

- VELTIN Gel should be used with caution in patients with a history of colitis.
- VELTIN Gel should be used with caution in patients with a history of allergic reactions to antibiotics.

**Usage**

- VELTIN Gel is not recommended for use in children under 12 years of age.

**Storing and Handling**

- Keep VELTIN Gel and all medicines out of the reach of children.
- Do not use VELTIN Gel after the expiration date.
- Protect from freezing.

**Legal Information**

- VELTIN is a registered trademark of Astellas Pharma Europe B.V.
- © 2016 Aqua Pharmaceuticals
- Exton, PA 19341

**References**

- Information from the package insert for VELTIN Gel.
- Clinical studies and trials conducted by the manufacturer.

**Contact Information**

For medical advice about side effects, contact your pharmacist or healthcare provider. You may report side effects to FDA at 1-800-FDA-1088.