Patient Information
Retin-A Micro® (tretinoin) Gel microsphere, 0.1%, 0.08%, 0.06%, and 0.04% for topical use

Important information: Retin-A Micro® (tretinoin) Gel microsphere, 0.1%, 0.08%, 0.06%, and 0.04% for topical use

Do not use Retin-A Micro in your eyes, mouth, vagina or the corners of your nose.

What is Retin-A Micro? Retin-A Micro is a prescription medicine used on the skin (topical) to treat acne. Acne is a condition in which the skin has blackheads, whiteheads, and other pimples. It is a skin area with a modified sebaceous gland. Retin-A Micro is safe and effective in the treatment of other conditions.

It is not known if Retin-A Micro is safe and effective in children under 12 years of age.

What should I tell my doctor before using Retin-A Micro? Before using Retin-A Micro, tell your doctor about all of your medical conditions, including if you:

- have a skin condition called eczema.
- have a burn. You should not use Retin-A Micro until your skin has healed.
- have any other medical condition.
- are pregnant or plan to become pregnant. It is not known if Retin-A Micro will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Retin-A Micro passes into your breast milk.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and any skin products you use.

How should I use Retin-A Micro? Use Retin-A Micro exactly as your doctor tells you to use it.

Your doctor may change your dose of Retin-A Micro if you have skin irritation.

Before you apply Retin-A Micro, gently wash the affected area with mild, non-medicated soap. Rinse and pat dry your skin.

Apply Retin-A Micro every day in the evening, or as directed by your doctor.

Do not use more than Retin-A Micro than you need to cover the affected area and do not apply Retin-A Micro more than 1 time a day. Using too much Retin-A Micro may make the skin red, dry, and itchy, which could cause you to stop using it.

In a double-blind trial with 16 acne subjects comparing 12 weeks of treatment with Retin-A Micro (gel microsphere, 0.1%) vs. placebo (each group, the most frequently reported adverse events affect the skin and include dryness, redness, burning, or stinging. The most prevalent of the dermatologic adverse events in the 0.1% group was dryness (11% vs. 1% in placebo) and redness (5% vs. 1% in placebo).

If you have more questions about Retin-A Micro, feel free to ask your doctor.

End of full prescribing information. These highlights do not include all the information needed to use Retin-A Micro safely and effectively. See full prescribing information for Retin-A Micro.

WARNINGS AND PRECAUTIONS—

- Retin-A Micro should not be used on acne nodule or cystic skin lesions.
- Avoid exposure to sunlight including tangential sunlight (sun-tanning lamps) as it may increase skin sensitivity.
- Do not use Retin-A Micro if you have had sensitivity reactions to tretinoin or other retinoids.
- Avoid exposed skin for at least 12 hours after application.
- Do not use in sunburned or irritated skin.
- Use Retin-A Micro microsphere only during the active treatment phase.
Stimulates mitotic activity and increased turnover of follicular epithelial cells with decreased microcomedone formation. Additionally, tretinoin α Although tretinoin activates three members of the retinoic acid (RAR) family of nuclear receptors (RARα, RARβ, and RARγ), purified water, sorbic acid, and trolamine.

Carbomer 974P, cyclomethicone and dimethicone copolyol, disodium edetate, propylene glycol, purified water, benzyl alcohol, butylated hydroxytoluene, and benzoic acid. You can ask your pharmacist or doctor for information about side effects. If you would like more information, talk with your doctor.

Skin irritation. Retin-A Micro may cause skin dryness, redness, swelling, and itching. If you develop any symptoms, your doctor may tell you to stop using Retin-A Micro for a while, change your dose, decrease the number of times you apply Retin-A Micro, or completely stop treatment with Retin-A Micro. It is not known if Retin-A Micro is effective when used less than 1 time a day. The most common side effects of Retin-A Micro include skin burning and itching.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Retin-A Micro. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Retin-A Micro?

Store Retin-A Micro at room temperature between 68°F to 77°F (20°C to 25°C). Store Retin-A Micro Pump up right.

Keep Retin-A Micro and all medicines out of the reach of children.

**Table 1:** Mean Percent Reduction in Lesion Counts

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Non-inflammatory lesions</th>
<th>Inflammatory lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retin-A Micro (tretinoin) Gel microsphere, 0.1%</td>
<td>49%</td>
<td>32%</td>
</tr>
<tr>
<td>Vehicle Gel</td>
<td>22%</td>
<td>7%</td>
</tr>
</tbody>
</table>

**Table 2:** Mean Percent Reduction in Lesion Counts

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Non-inflammatory lesions</th>
<th>Inflammatory lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retin-A Micro (tretinoin) Gel microsphere, 0.04%</td>
<td>46%</td>
<td>47%</td>
</tr>
<tr>
<td>Vehicle Gel</td>
<td>17%</td>
<td>9%</td>
</tr>
</tbody>
</table>

**What are the possible side effects of Retin-A Micro?**

Retin-A Micro may cause serious side effects, including:

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