

Solagé[®] (so-la-jay) Topical Solution **(mequinol 2%, tretinoin 0.01%)**

Important: For skin use only

Read the Patient Information that comes with **Solagé** 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 to your doctor about your medical condition or treatment.

What is Solagé?

Solagé is a prescription medicine used on the skin to treat solar lentigines. Solar lentigines are also called “brown spots”, “age spots”, or “liver spots”. Solar lentigines can happen on areas of skin that have been exposed to too much sunlight over time.

Solagé should only be used under medical care along with a skin care and sun avoidance program.

Who should not use Solagé Solution?

Do not use **Solagé** if you are:

- **a woman who is pregnant, planning to become pregnant, or is able to become pregnant.** **Solagé** may harm a fetus (unborn baby).
- **allergic to anything in Solagé.** See the end of this leaflet for a list of ingredients in **Solagé**.

Solagé has not been studied in children and should not be used on children.

Solagé may not be right for you. Before stating Solagé, tell your doctor about all of your health conditions, including, if you:

- have eczema
- have skin irritation
- have vitiligo or a family history of vitiligo. Vitiligo is a condition where color is lost on areas of the skin and white patches appear.
- have a sunburn
- have skin that is sensitive to sunlight
- are exposed to sunlight often because of your job
- are breastfeeding. It is not known if **Solagé** passes into breast milk and to our baby.

Tell your doctor about all of the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements. Solagé should not be used with other medicines that can make your skin sensitive to sunlight including:

- blood pressure medicines called “thiazides”
- some antibiotic medicines (tetracyclines, fluoroquinolones or sulfonamides)
- antipsychotic medicines called “phenothiazines”

Know the medicines you take. Keep a list of your medicines with you to show your doctor. Your doctor will decide if you can use **Solagé** with your other medicines.

Tell your doctor about all of the skin products you use. Your doctor will tell you which skin products you can use with **Solagé**. **You must be careful about using skin products that can dry or irritate your skin because dryness and irritation are increased with Solagé.** Skin products that can dry and irritate your skin include:

- products that contain alcohol, astringents, spices, or lime
- medicated soaps or shampoos
- hair “perms”
- hair removal products such as electrolysis, depilatories, or waxes

How should I use Solagé Solution?

- **Solagé is for skin use only.**
- Apply Solagé exactly as prescribed and instructed by your doctor. Solagé is usually applied twice a day, at least 8 hours apart. Do not use more Solagé or use it more often than prescribed.
- Apply Solagé to the “spots” to be treated using the applicator tip of the **Solagé** bottle. Be careful and do not apply Solagé to “normal” skin.
- **Do not use Solagé around your eyes, mouth, crease of your nose, or on mucous membranes.** Solagé can cause severe redness, itching, burning, stinging, and peeling if applied to these areas. If Solagé gets in your eyes, rinse them well with water and call your doctor right away. If you get **Solagé** in your mouth or swallow any, get medical treatment right away.
- Do not bathe or shower for at least 6 hours after applying Solagé.
- Cosmetics may be applied 30 minutes after using **Solagé**. Talk to your doctor about cosmetics and other skin care products that are okay to use with Solagé.
- You must avoid sun exposure (including the use of sunlamps). Always wear protective clothing when you go outside. If your skin gets sunburned, stop Solagé until the sunburn has healed.

What are the possible side effects of Solagé Solution?

Common side effects of **Solagé** include **redness, stinging, burning, tingling, peeling, itching, or irritation on areas of the skin where it is applied.**

Solagé may cause the treated age spots or surrounding skin to become lighter than your normally colored skin, especially if too much Solagé is used or it is used for too long. Call your doctor if your skin becomes lighter than normal. Skin color may return when Solagé is stopped.

These are not all of the side effects of Solagé Solution. Ask your doctor or pharmacist for more information.

How should I store Solagé?

- Store **Solagé** at room temperature, between 59° to 86° F (15° to 30°C). Protect **Solagé** from light by returning the bottle to the carton after each use.

Solagé is flammable. Keep away from heat and flames.

- **Keep Solagé and all medications out of reach of children.**

General information about Solagé.

Medicines can be prescribed for conditions that are not in patient information leaflets. Use **Solagé** only for what your doctor prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives the most important information about **Solagé**. For more information about **Solagé**, talk with your doctor or pharmacist. For more information call 866-440-5508 or visit www.solage.com.

What are the ingredients in Solagé?

Active Ingredients: mequinol and tretinoin

Inactive Ingredients: ethyl alcohol (77.8% v/v), polyethylene glycol 400, butylated hydroxytoluene, ascorbic acid, citric acid, ascorbyl palmitate, edetate disodium, and purified water.

Marketed by:

Barrier Therapeutics, Inc.

Princeton, NJ 08540-6697 USA

Manufactured by:

Contract Pharmaceutical Laboratories

Buffalo, NY 14213 USA

Revised December 2005