HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SOLAGÉ safely and effectively. See full prescribing information for SOLAGÉ.

SOLAGÉ® (mequinol and tretinoin) topical solution
Initial U.S. Approval: 1999

----------RECENT MAJOR CHANGES----------

Contraindications (4)	Removed 12/2019
Warnings and Precautions (5.1)	12/2019

----------INDICATIONS AND USAGE----------
Solagé is a combination of mequinol, a skin lightening agent, and tretinoin, a retinoid, indicated for the treatment of solar lentigines, as an adjunct to a comprehensive skin care and sun avoidance program where the patient should primarily either avoid the sun or use protective clothing. (1)

Limitations of Use
The safety or effectiveness of Solagé for the prevention or treatment of melasma or postinflammatory hyperpigmentation has not been established.(1)

----------DOSAGE AND ADMINISTRATION----------
- Apply twice daily to the affected area. (2)
- Not for oral, ophthalmic or intravaginal use.(2)
- Do not apply on non-intact skin. (2)

----------DOSAGE FORMS AND STRENGTHS----------
Topical solution: mequinol 2% and tretinoin 0.01%, by weight. (3)

----------CONTRAINDICATIONS----------
None.

----------WARNINGS AND PRECAUTIONS----------
- *Risk of Embryofetal Toxicity*: Based on findings in animal studies, Solagé may cause fetal harm. Avoid use in pregnant women. (5.1)
- *Phototoxicity and Risk of Sunburn*: Minimize exposure to sunlight and sunlamps. Use sunscreen and protective clothing when sun exposure cannot be avoided. Do not use concomitantly with drugs known to be photosensitizers. (5.2, 7)
- *Local Adverse Reactions*: Solagé is a dermal irritant and may cause skin irritation, erythema, burning, stinging or tingling, peeling, and pruritis. Avoid use on irritated or eczematous skin. Avoid concomitant use of topical products with a strong skin drying effect. (5.3)
- *Hypopigmentation:* Use with caution in patients with a history or family history of vitiligo. (5.4)
- *Flammable Contents:* Keep away from heat and open flames. (5.5)

----------ADVERSE REACTIONS----------
The most common adverse reactions (≥ 5%) were erythema, burning, stinging or tingling, desquamation, pruritus, skin irritation, halo hypopigmentation, and hypopigmentation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Almirall, LLC at 1-866-665-2782 or FDA at 1-800- FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------
Pregnancy: Avoid use in pregnant women. (8.1)

See 17 for FDA-approved patient labeling.

Revised: 12/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Solagé® (mequinol 2%, tretinoin 0.01%) is indicated for the treatment of solar lentigines, as an adjunct to a comprehensive skin care and sun avoidance program where the patient should primarily either avoid the sun or use protective clothing.

Limitations of Use:
The safety or effectiveness of Solagé for the prevention or treatment of melasma or postinflammatory hyperpigmentation has not been established.

2 DOSAGE AND ADMINISTRATION

Apply Solagé to the solar lentigines using the applicator tip while avoiding application to the surrounding skin. Use twice daily, morning and evening at least 8 hours apart. Patients should not shower or bathe the treatment areas for at least 6 hours after application of Solagé.

Not for oral, ophthalmic or intravaginal use. Special caution should be taken when applying Solagé to avoid the eyes, mouth, paranasal creases, and mucous membranes.

Do not apply to non-intact skin *[see Warnings and Precautions (5.1, 5.3)]*.

Improvement continues gradually through the course of therapy and should be apparent by 24 weeks. Patients should avoid exposure to sunlight (including sunlamps) or wear protective clothing while using Solagé *[see Warnings and Precautions 5.2]*.

With discontinuation of Solagé therapy, a majority of patients will experience some repigmentation of their lesions over time.

Applications of larger amounts of medication or more frequently than recommended will not lead to more rapid or better results, and may lead to marked redness, peeling, irritation, or hypopigmentation of the skin *[see Adverse Reactions (6.1)]*.

Patients treated with Solagé may use cosmetics but should wait 30 minutes before applying.

Avoid concomitant use of topical products with a strong skin drying effect or other potentially irritating topical products *[see Warnings and Precautions (5.2)]*.

3 DOSAGE FORMS AND STRENGTHS

Mequinol 2% and tretinoin 0.01%, by weight, in a solution base of ethyl alcohol (77.8% v/v).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Embryofetal Toxicity

Based on findings in animal studies, Solagé may cause fetal harm. Avoid use in pregnant women *[see Use In Specific Populations (8.1)]*.

5.2 Phototoxicity and Risk of Sunburn

Because of heightened burning susceptibility, avoid or minimize exposure to sunlight (including sunlamps) to treated areas during the use of Solagé. Patients must be advised to use protective clothing and comply with a comprehensive sun avoidance program (including using sunscreen) when using Solagé. Patients with sunburn should be advised not to use Solagé until fully recovered. Patients who may have considerable sun exposure due to their occupation and those patients with inherent sensitivity to sunlight should exercise particular caution when using Solagé.

Solagé should not be administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides,

tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

5.3 Local Adverse Reactions

Solagé is a dermal irritant and the results of continued irritation of the skin for greater than 52 weeks in chronic, long-term use are not known.

Tretinoin has been reported to cause severe irritation of eczematous skin, including the development of skin fissures. Solagé should be used with caution in patients with this condition.

Solagé may cause skin irritation, erythema, burning, stinging or tingling, peeling, and pruritis. If the degree of such local irritation warrants, patients should be directed to use less medication, decrease the frequency of application, discontinue use temporarily, or discontinue use altogether. The efficacy at reduced frequencies of application has not been established.

Avoid concomitant use of other potentially irritating topical products (such as products with high concentration of alcohol, astringents, spices or lime, medicated soaps or shampoos, permanent wave solutions, electrolysis, hair depilatories or waxes, or products with a strong skin drying effect). Weather extremes, such as wind or cold may be more irritating to patients using Solagé.

5.4 Hypopigmentation

Hypopigmentation has occurred with Solagé use. Solagé should be used with caution by patients with a history, or family history, of vitiligo, as they might be more susceptible to hypopigmentation, which can also be more severe in these patients.

5.5 Flammable Contents

Keep away from heat and open flame.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The initial clinical trials for Solagé included 1794 subjects of Skin Type I-V, 94.5% of whom were Caucasian. The trials also included 5% of subjects who were Asian/Pacific Islander (1.2%), African-American (0.8%), and Hispanic/Latino (3.5%).

In the pivotal clinical trials, adverse reactions were primarily mild to moderate in intensity, occurring in 66% and 30% of subjects, respectively. The majority of these events were limited to the skin and 64% had an onset of a skin related adverse reaction early in treatment (by week 8).

The most frequent adverse reactions in subjects treated with Solagé were erythema (49%), burning, stinging, or tingling (26%), desquamation (14%), pruritus (12%), and skin irritation (5%). Some subjects experienced temporary hypopigmentation of treated lesions (5%) or of the skin surrounding treated lesions (7%). Ninety-four of 106 subjects (89%) had resolution of hypopigmentation upon discontinuation of treatment to the lesion, and/or re-instruction on proper application to the lesion only. Another 8% (9/106) of subjects with hypopigmentation events had resolution within 120 days after the end of treatment. Three of the 106 subjects (2.8%) had persistence of hypopigmentation beyond 120 days. Hypopigmentation of the skin surrounding treated lesions occurs even in the setting of proper application of the drug within the lesion border. One subject in the trials, whose brother had vitiligo, experienced hypopigmentation in areas that had not been treated with study medication. Some of these areas continued to worsen for at least one month post treatment with Solagé. Six weeks later the severity of the hypopigmentation had decreased from moderate to mild and 106 days post treatment, subject had resolution of some but not all lesions.

Approximately 6% of subjects discontinued study participation due to adverse reactions. These discontinuations were due primarily to skin redness (erythema) or related cutaneous adverse reactions.

Adverse drug reactions that were reported in greater than 1% of subjects appear in Table 1 below.

Table 1. Adverse Reactions Occurring in >1% of the Population – All Studies

Body System	Solagé (mequinol 2% tretinoin 0.01%)		Tretinoin, 0.01%		Mequinol, 2%,		Vehicle	
Skin and Appendages	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Erythema	613	41.1	261	55.3	13	5.1	8	4.6
Burning/Stinging/ Tingling	270	18.1	173	36.7	26	10.2	20	11.4
Desquamation	171	11.5	93	19.7	7	2.8	2	1.1
Pruritus	148	9.9	66	14.0	12	4.7	3	1.7
Irritation Skin*	90	6.0	25	5.3	1	0.4	1	0.6
Halo Hypopigmentation	96	6.4	16	3.4	2	0.8	2	1.1
Hypopigmentation	62	4.2	8	1.7	2	0.8	0	0.0
Skin Dry	46	3.1	18	3.8	3	1.2	1	0.6
Rash	31	2.0	21	4.4	0	0.0	1	0.6
Crusting	30	2.0	18	3.8	0	0.0	1	0.6
Rash Vesicular Bullae	18	1.2	8	1.7	0	0.0	0	0.0
Dermatitis	29	1.9	0	0.0	0	0.0	0	0.0
Discomfort Skin	52	3.5	0	0.0	0	0.0	0	0.0
Irritant Dermatitis	17	1.1	0	0.0	0	0.0	0	0.0

*In study RD.06.SRE.18091 irritant dermatitis included signs & symptoms of scaling, dryness, stinging/burning, and erythema.

Over 150 subjects used Solagé twice daily for 52 weeks in an open label clinical study. The safety profile for Solagé in this long-term study was similar to that seen in the 24- week studies.

Over 90 subjects used Solagé twice daily and a concomitant sunscreen daily for up to 24 weeks in an open label clinical study. The safety profile for Solagé in this study was similar to that seen in studies which prohibited sunscreen use.

An additional open label study was conducted in 259 subjects in the Asian (24.3%), Hispanic/Latino (62.2%), and African American (13.5%) ethnic groups with skin types II to V. This number reflects approximately three times as many subjects in this population as were represented in the initial clinical trials. In this study, as in the earlier studies, Solagé was used twice daily for a period of 24 weeks. The overall safety profile in this study was generally consistent with the initial clinical trials.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Solagé should be avoided by pregnant women. Solagé contains tretinoin and ethyl alcohol. The systemic levels of ethyl alcohol were not assessed and the systemic levels for tretinoin following topical administration are lower than with oral tretinoin, however absorption of this product may result in fetal exposure. Available data from published observational studies of topical tretinoin in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are case reports of major birth defects observed with the use of

other topical tretinoin products that were similar to those seen in fetuses exposed to oral retinoids, but these case reports do not establish a pattern or association with tretinoin-related embryopathy. There are no data on mequinol or Solagé use in pregnant women.

In animal reproduction studies with pregnant rabbits dosed topically with Solagé during organogenesis, there were incidences of known retinoid malformations, including hydrocephaly, cleft palate and appendicular skeletal defects (see Data). The available data do not support relevant comparisons of systemic mequinol and tretinoin exposures achieved in the animal studies to exposures observed in humans after topical use of Solagé.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Data

Animal Data

Topical administration of mequinol and tretinoin or tretinoin alone to pregnant rabbits during organogenesis was associated with marked hydrocephaly with visible doming of the head observed in one mid-dose litter (12 and 0.06 mg/kg or 132 and 0.66 mg/m^2 of mequinol and tretinoin, respectively) and two fetuses in one high dose litter (40 and 0.2 mg/kg or 440 and 2.2 mg/m^2 of mequinol and tretinoin, respectively) treated with Solagé, and two high-dose litters treated with tretinoin (0.2 mg/kg, 2.2 mg/m^2). These malformations were considered to be treatment related and due to the known effects of tretinoin. This was further supported by coincident appearance of other malformations associated with tretinoin, such as cleft palate and appendicular skeletal defects. No effects attributed to treatment were observed in rabbits in that study treated topically with mequinol alone (dose 40 mg/kg, 440 mg/m^2). A no-observed-effect level (NOEL) for malformations in rabbits was established at 4 and 0.02 mg/kg or 44 and 0.22 mg/m^2 mequinol and tretinoin, respectively. Plasma tretinoin concentrations were not raised above endogenous levels, even at doses where malformations were observed.

In a repeated study in pregnant rabbits administered the same topical dose levels as the study described above, additional precautionary measures were taken to prevent ingestion, although there is no evidence to confirm that ingestion occurred in the initial study. Precautionary measures additionally limited transdermal absorption to a six hour exposure period, or approximately one-fourth of the human clinical daily continuous exposure time. This study did not show any significant malformations at doses up to 40 and 0.2 mg/kg or 440 and 2.2 mg/m^2 of mequinol and tretinoin, respectively. However, a concurrent tretinoin dose group (0.2 mg/kg/day) did include two litters with limb malformations.

Topical administration of Solagé to pregnant rats during organogenesis did not cause malformations at doses of 80 and 0.4 mg/kg mequinol and tretinoin, or 480 and 2.4 mg/m^2.

8.2 Lactation

Risk Summary

There are no data on the presence of topical tretinoin, mequinol or their metabolites in human milk, the effects on the breastfed infant or the effects on milk production. It is possible that topical administration of large amounts of Solagé could result in sufficient systemic absorption to produce detectable quantities in human milk *(see Clinical Considerations).* The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Solagé and any potential adverse effects on the breastfed infant from Solagé or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use Solagé on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply Solagé directly to the nipple and areola to avoid direct infant exposure.

8.4 Pediatric Use

The safety and effectiveness of Solagé have not been established in pediatric patients.

8.5 Geriatric Use

Of the total number of subjects in clinical studies of Solagé, approximately 43% were 65 and older, while approximately 8% were 75 and over. No overall differences in effectiveness or safety were observed between these patients and younger

patients.

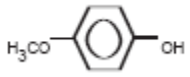
10 OVERDOSAGE

Oral ingestion of the drug may lead to the same adverse effects as those associated with excessive oral intake of vitamin A (hypervitaminosis A). If oral ingestion occurs, the patient should be monitored, and appropriate supportive measures should be administered as necessary.

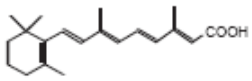
11 DESCRIPTION

Solagé (mequinol and tretinoin) topical solution, contains mequinol 2%, a skin lightening agent, and tretinoin 0.01%, a retinoid by weight.

Mequinol is 4-hydroxyanisole, the monomethyl ether of hydroquinone or 1-hydroxy-4-methoxybenzene. It has the chemical formula, $C_7H_8O_2$, a molecular weight of 124.14, and the structural formula:



The chemical name for tretinoin, a retinoid, is (all-*E*)-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid, also referred to as all-*trans*-retinoic acid. It has the chemical formula, $C_{20}H_{28}O_2$, a molecular weight of 300.44, and the structural formula:



Solagé is in a solution base of ethyl alcohol (77.8% v/v), polyethylene glycol 400, butylated hydroxytoluene, ascorbic acid, citric acid, ascorbyl palmitate, edetate disodium, and purified water.

12 CLINICAL PHARMACOLOGY

Solar lentigines are localized, pigmented, macular lesions of the skin on the areas of the body which have been chronically exposed to sunlight. Biopsy specimens of solar lentigines were collected in a clinical study with Solagé at baseline, at the end of a 24- week treatment period, and at the end of a subsequent 24- week, no treatment, follow-up period. The end of treatment specimens showed a decrease in melanin pigmentation in both melanocytes and keratinocytes, and an increased lymphocytic infiltration, which may have been the result of irritation or an immunologic reaction. The end of follow-up period specimens showed repigmentation of the melanocytes and keratinocytes to a state similar to the baseline specimens. These results indicate that there is no assurance that any improvement obtained would persist upon discontinuation of drug therapy.

12.1 Mechanism of Action

The mechanism of action of mequinol and tretinoin for the treatment of solar lentigines is unknown.

12.3 Pharmacokinetics

The percutaneous absorption of tretinoin and the systemic exposure to tretinoin and mequinol were assessed in healthy subjects (n=8) following two weeks of twice daily topical treatment of Solagé. Approximately 0.8 mL of Solagé was applied to a 400 cm^2 area of the back, corresponding to a dose of 37.3 µg/cm^2 for mequinol and 0.23 µg/cm^2 for tretinoin. The percutaneous absorption of tretinoin was approximately 4.4%, and systemic concentrations did not increase over endogenous levels. The mean C_{max} for mequinol was 9.92 ng/mL (range 4.22 to 23.62 ng/mL) and the T_{max} was 2 hours (range 1 to 2 hours).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

A dermal carcinogenicity study in mice demonstrated that Solagé applied topically at daily doses up to 80 and 0.4 mg/kg or 240 and 1.2 mg/m^2 of mequinol and tretinoin, respectively, was not carcinogenic.

Mequinol was non-mutagenic in the Ames/Salmonella assay using strains TA98, TA100, TA1535, and TA1537, all of which are insensitive to mutagenic effects of structurally-related quinones. Solagé was non-genotoxic in an in vivo dermal

micronucleus assay in rats, but exposure of bone marrow to drug was not demonstrated.

No impairment of fertility was observed in rats dosed topically with Solagé at a daily dose of 80 and 0.4 mg/kg or 480 and 2.4 mg/m^2 of mequinol and tretinoin, respectively.

14 CLINICAL STUDIES

Two adequate and well-controlled trials evaluated changes in treated hyperpigmented lesions on the face, forearms/back of hands in 421 subjects treated with Solagé, 422 subjects treated with tretinoin topical solution, 209 subjects treated with mequinol topical solution and 107 subjects treated with vehicle for up to 24 weeks. In these trials, subjects were to avoid sun exposure and use protective clothing, and use of sunscreens was prohibited. Subjects were allowed to apply moisturizing lotion 30 minutes after application of Solagé. Physicians assessed the extent of improvement or worsening of all the treated lesions from the baseline condition on a 7-point scale. The results of these evaluations are shown in Table 2 below.

Table 2. Physician Assessment of Change in Hyperpigmentation of Treated Lesions Through 24 Weeks

	Face		**Forearms/Back of Hands**	
	Solagé Solution (N=422)	**Vehicle (N=107)**	**Solagé Solution (N=421)**	**Vehicle (N=107)**
Moderate or greater[1] Improvement	57%	15%	54%	14%
Slight Improvement	28%	36%	26%	33%
No Change[2]	15%	49%	20%	53%

1 Includes the following grades: Moderate Improvement, Marked Improvement, Almost Clear, Completely Clear. Moderate or greater improvement was considered clinically meaningful.

2 Includes the following grades: No Change, Worse (less than 1% of patients treated with Solagé were rated as worse).

Improvement (lightening) of the solar lentigines occurred gradually over time during the 24- week treatment period. At 24 weeks of treatment, 57% and 54% of subjects experienced moderate improvement or greater, and 3% and 1% of subjects were completely clear of all treated lesions for the face and forearms/back of hands, respectively. There are no vehicle-controlled effectiveness data on the course of lesions treated beyond 24 weeks.

After 24 weeks of treatment, for the forearm/back of hands treatment site, the percentage of subjects treated with tretinoin topical solution that experienced moderate improvement or greater, slight improvement, or no change, were 38%, 37%, and 26%, respectively, and for mequinol topical solution were 24%, 40%, and 36%, respectively. For the face treatment site, the percentage of subjects treated with tretinoin topical solution that experienced moderate improvement or greater, slight improvement, or no change, were 46%, 33%, and 21%, respectively, and for mequinol topical solution were 33%, 30%, and 37% respectively.

The duration of effect was investigated during a period of up to 24 weeks following the discontinuation of treatment. Results from these studies showed that patients may maintain the level of clinical improvement of their treated lesions from the end of treatment through the 24- week follow-up period. However, some degree of repigmentation of treated lesions was observed over time, demonstrating reversibility of the depigmenting action of Solagé.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Solagé (mequinol 2%, tretinoin 0.01%) topical solution is available in 30mL plastic bottles with an applicator.
NDC xxxxx-xxx-xx

16.2 Storage Conditions
The bottle should be protected from light by continuing to store in the carton after opening. Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F).
FLAMMABLE. Keep away from heat and open flame.
Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Patient Information).

Risk of Embryofetal Toxicity
Based on findings in animal studies, Solagé may cause fetal harm. Avoid use in pregnant women.

Photosensitivity and Risk of Sunburn
Advise patients to avoid excessive sun exposure and to use of sunscreens and protective measures (hat, visor). Advise patients to avoid using Solagé if also taking other medicines may increase sensitivity to sunlight.

Lactation
Advise a woman to use Solagé on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply Solagé directly to the nipple and areola to avoid direct infant exposure.

Important Administration Instructions
Advise patients of the following:
1. Use Solagé twice daily, morning and evening at least 8 hours apart.
2. Apply Solagé to the solar lentigines using the applicator tip while avoiding application to the surrounding skin.
3. Do not apply to non-intact skin.
4. Avoid concomitant use of topical products with a strong drying or irritating effect.
5. Advise patients not to use more than the recommended amount and not to apply more than twice daily as this will not produce faster or better results but may increase irritation and hypopigmentation.

PATIENT INFORMATION

SOLAGÉ® (so-la-jay)

(mequinol and tretinoin)

topical solution

Important information: Solagé is for skin use only (topical use). Solagé is not for use in your mouth, eyes or vagina.

What is Solagé?

Solagé is a prescription medicine used on the skin (topical) to treat skin solar lentigines. Solar lentigines are also called “brown spots”, “age spots”, or “liver spots”.

- Solagé should be used along with a skin care and sun avoidance program.
- It is not known if Solagé is safe and effective for the prevention or treatment of certain other dark spots on the skin.
- It is not known if Solagé is safe and effective in children.

Before using Solagé, tell your healthcare provider about all of your medical 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. You should not use Solagé until your skin has healed.
- have skin that is sensitive to sunlight
- are exposed to sunlight often because of your job
- are pregnant or plan to become pregnant. Solagé may harm your unborn baby. You should not use Solagé if you are pregnant. Stop using Solagé if you become pregnant and call your healthcare provider.
- are breastfeeding or plan to breastfeed. It is not known if Solagé passes into your breast milk . If you breastfeed during treatment with Solagé, use Solagé on the smallest area of the skin and for the shortest time needed. Do not apply Solagé directly to the nipple and areola to avoid contact with your baby.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements. Solagé should not be used with other medicines that can make your skin sensitive to sunlight.

Tell your healthcare provider about all of the skin products you use. Your doctor will tell you which skin products you can use with Solagé. You should avoid using skin products that can dry or irritate your skin . Skin products that may increase dryness or irritation of your skin during treatment with Solagé include:

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

How should I use Solagé?

- Use Solagé exactly as your healthcare provider tells you.
- Do not use more Solagé than you need to cover the affected area and do not apply Solagé more than 2 times a day. Using too much Solagé or using it too often will not give you faster or better results, and may cause skin redness, peeling, discomfort, or skin discoloration.
- Apply Solagé 2 times a day, in the morning and evening, at least 8 hours apart.
- Apply Solagé to the affected areas using the applicator tip of the Solagé bottle. Do not apply Solagé to open (non- intact) and unaffected skin areas.
- Do not use Solagé around your eyes, mouth, the corners of your nose, or on mucous membranes.
- Do not bathe or shower for at least 6 hours after applying Solagé.
- You may use cosmetics 30 minutes after applying Solagé.
- If Solagé is swallowed, call your healthcare provider or get medical help right away.

What should I avoid while using Solagé?

- You should avoid sunlight, sunlamps, tanning beds, and ultraviolet light during treatment with Solagé. Use sunscreen and wear protective clothing and hats if you must be in the sunlight. If your skin gets sunburned, stop using Solagé until the sunburn has healed.
- Wind or cold weather may irritate skin treated with Solagé.

What are the possible side effects of Solagé?

Solagé can cause serious side effects, including:

- **Sensitivity to sunlight (photosensitivity).** See **"What should I avoid while using Solagé?"**
- **Skin irritation** is common with Solagé and can be severe in some people. Solagé may cause skin irritation, such as redness, burning, stinging or tingling, peeling and itching. Your healthcare provider may tell you to use less Solagé, decrease how often you use Solagé, temporarily stop or completely stop treatment with Solagé if you have skin irritation.
- **Skin discoloration (hypopigmentation)** is common with Solagé and can be severe in some people. Solagé may cause the treated skin areas or surrounding skin to become lighter than your normal colored skin, especially if you use too much Solagé or use it longer than prescribed. Skin color may return to normal when you stop using Solagé.

These are not all of the possible side effects of Solagé. 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 Solagé?

- Store Solagé at 77 ºF (25ºC) .
- 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 medicines out of the reach of children.

General information about the safe and effective use of Solagé.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Solagé for a condition for which it was not prescribed. Do not give Solagé to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about Solagé that is written for health professionals.

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.

Manufactured for: Almirall, LLC, Exton, PA 19341

almirall

For more information call 1-866-665-2782

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 12/2019