PRESCRIBING INFORMATION

PrSOLUGEL®

benzoyl peroxide gel USP, 8% w/w

SOLUGEL®

benzoyl peroxide gel USP, 4% w/w

ACNE THERAPY

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THERAPEUTIC CLASSIFICATION

Acne therapy

ACTION AND CLINICAL PHARMACOLOGY

Benzoyl peroxide is a highly lipophilic oxidizing agent with bacteriocidal activity, against *Propionibacterium acnes* (*P. acnes*) which is present in the acne-affected pilosebaceous unit. Additionally, benzoyl peroxide has demonstrated keratolytic effects.

INDICATIONS AND CLINICAL USE

SOLUGEL® Gel (benzoyl peroxide USP) is indicated for the treatment of mild to moderate acne vulgaris.

CONTRAINDICATIONS

SOLUGEL® is contraindicated in patients with known hypersensitivity to benzoyl peroxide or to any of the ingredients in the formulation. For a complete listing, see Description and Composition section.

WARNINGS AND PRECAUTIONS

For external use only. Contact with the eyes, eyelids, mouth, lips, other mucous membranes (i.e., nostrils) and broken skin should be avoided. If contact occurs, rinse thoroughly with water.

Care should be taken when applying SOLUGEL® Gel to the neck and other sensitive areas.

During the first weeks of treatment, a sudden increase in peeling and reddening will occur in most patients and will normally subside in a day or two if treatment is temporarily discontinued.

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.

As benzoyl peroxide may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight should be avoided or minimised. When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.

The product may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents. If this occurs, only one product should be used unless directed by a health care practitioner.

If severe local irritancy occurs (e.g. severe erythema, severe dryness and itching, severe stinging/burning sensation), benzoyl peroxide should be discontinued. If irritation persists, patients should consult a health care practitioner.

Special Populations

Pregnant Women: There are limited data on the use of topical benzoyl peroxide in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

In a combined repeat- dose and reproduction/development toxicity study, benzoyl peroxide (250, 500 or 1,000 mg/kg/day) was administered orally to male rats for 29 days and female rats for 41-51 days. There were no treatment-related changes observed in the mating period, mating rate, conception rate, delivery rate, birth rate, pregnancy period, luteinization number, implantation number and the rate of losing embryos and foetuses after implantation. In pups, body weight was significantly decreased in the high-dose group. The no-observed-adverse-effect-level (NOAEL) for reproductive toxicities was considered to be 500 mg/kg/day.

No effects during pregnancy are anticipated since systemic exposure to benzoyl peroxide is very limited.

However, benzoyl peroxide should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Nursing Mothers: Percutaneous absorption of benzoyl peroxide is very limited; however, it is not known whether benzoyl peroxide is excreted in human milk after topical application.

Topical benzoyl peroxide should be used during lactation only if the expected benefit justifies the potential risk to the infant.

If used during lactation, benzoyl peroxide should not be applied to the breast area to avoid accidental oral ingestion by the infant.

Pediatrics (< 12 years of age): Safety and effectiveness of topical benzoyl peroxide in children under the age of 12 has not been established.

Geriatrics (> 65 years of age): Safety and effectiveness of benzoyl peroxide in geriatric patients of age 65 years and above has not been established.

Patients with Renal/Hepatic Impairment: No dosage adjustment is necessary. As there is very limited percutaneous absorption of benzoyl peroxide following topical application, renal/hepatic impairment is not expected to result in systemic exposure of clinical significance.

ADVERSE REACTIONS

Clinical Trial Data

Skin and subcutaneous tissue disorders:

Very common (≥ 10%): peeling, application site erythema

Common (≥ 1% to < 10%): dryness, pruritus and contact sensitisation reactions

Uncommon (≥ 0.1% to < 1%): burning sensation

Post-Market Adverse Drug Reactions

General disorders and administrative site conditions: application site discoloration and application site reactions such as irritation and pain, dry lips, cheilitis.

Immune system disorders: allergic reactions, including application site hypersensitivity and anaphylaxis, lip swelling, urticaria and swelling of the face.

Skin and subcutaneous tissue disorders: application site rash, dermatitis, skin exfoliation and photosensitivity.

DRUG INTERACTIONS

Concomitant application of benzoyl peroxide with tretinoin, isotretinoin,and tazarotene should be avoided since it may reduce their efficacy and increase irritation. If combination treatment is required, the products should be applied at different times of the day (e.g., one in the morning and the other in the evening.)

Using topical benzoyl peroxide at the same time as topical sulfonamide-containing products may cause skin and facial hair to temporarily change colour (yellow/orange).

DOSAGE AND ADMINISTRATION

Adults and children 12 years of age and older:

Wash hands and affected area thoroughly with a non-medicated soap (contains no benzoyl peroxide) and water before use.

Benzoyl peroxide should be applied in a thin film over the entire affected area once or twice daily, or as directed by a health care practitioner, preferably after washing and drying the skin. Because excessive drying of the skin may occur, the patient should start with one application daily, and then gradually increase to two times daily if needed.

If excessive dryness or peeling occurs, frequency of application should be reduced or application temporarily interrupted, per physician instruction or patient tolerability.

Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continued use is normally required to maintain a clinical response.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Topically applied benzoyl peroxide is not generally absorbed in sufficient amounts to produce systemic effects.

Excessive application may result in severe irritation. In this event, discontinue use and wait until the skin has recovered.

Cold compresses can provide relief from irritation due to excessive application.

Accidental ingestion of topical benzoyl peroxide should be managed clinically.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DESCRIPTION AND COMPOSITION

SOLUGEL® (benzoyl peroxide gel USP, 8% w/w) and SOLUGEL® (benzoyl peroxide gel USP, 4% w/w) are white smooth gels.

Composition:

Each gram of SOLUGEL® Gel 4% (benzoyl peroxide gel USP, 4% w/w) contains 58.71 mg benzoyl peroxide. Each gram of SOLUGEL® Gel 8% (benzoyl peroxide gel USP, 8% w/w) contains 117.34 mg benzoyl peroxide. SOLUGEL® Gel 4% and SOLUGEL® Gel 8% also contain cetyl alcohol, promulgen G, simethicone, dimethyl isosorbide, fragrance, sodium hydroxide and purified water.

AVAILABILITY

SOLUGEL® Gel 8% (benzoyl peroxide gel USP, 8% w/w), 45 g tube.

SOLUGEL® Gel 4% (benzoyl peroxide gel USP, 4% w/w), 45 g tube.

STORAGE

Store at controlled room temperature, 15º – 30ºC.

CONSUMER INFORMATION

PrSOLUGEL®
benzoyl peroxide gel USP, 8% w/w

SOLUGEL®
benzoyl peroxide gel USP, 4% w/w

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SOLUGEL®. Read all of this leaflet carefully before you start using SOLUGEL®. Certain SOLUGEL® products are available without prescription. However, you still need to use SOLUGEL® carefully to get the best results from it. Keep this leaflet. You may need to read it again. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SOLUGEL® Gel is used for the treatment of mild to moderate acne.

What it does:

SOLUGEL® works by fighting the bacteria that can cause acne.

When it should not be used:

SOLUGEL® should not be used:

- if you are allergic (hypersensitive) to benzoyl peroxide or any of the ingredients in SOLUGEL® (see What the medicinal ingredient is and What the nonmedicinal ingredients are). If you think this applies to you, don't use SOLUGEL® until you have checked with your doctor or pharmacist.

What the medicinal ingredient is:

benzoyl peroxide.

What the important nonmedicinal ingredients are:

cetyl alcohol, dimethyl isosorbide, fragrance, promulgen G, simethicone, sodium hydroxide and purified water.

What dosage forms it comes in:

SOLUGEL® Gel 8%
SOLUGEL® Gel 4%

WARNINGS AND PRECAUTIONS

Before using SOLUGEL®, talk to your doctor or pharmacist if:

- you are pregnant or planning to become pregnant. If you do become pregnant during treatment with SOLUGEL® tell your doctor.
- you are breastfeeding. It is not known whether the ingredients of SOLUGEL® can pass into breast milk. If you are breastfeeding, you must check with your doctor or pharmacist before using SOLUGEL®. If you do use SOLUGEL® when breastfeeding, do not use on your breast area to ensure that the baby does not accidentally get it in their mouth.

The safety and effectiveness of SOLUGEL® in children under the age of 12 has not been established.

The safety and effectiveness of SOLUGEL® in patients 65 years and above has not been established.

Tell your doctor or pharmacist if you're using or have recently used any other medicines for acne. This includes medicines bought without a prescription.

SOLUGEL® is for external use only. Avoid contact with the eyes, eyelids, mouth, lips, other mucous membranes such as inside the nose and broken skin such as cuts or scrapes. If contact with these areas occurs, rinse with water immediately.

Take care when applying SOLUGEL® Gel to the neck and other sensitive areas, since skin irritation is more likely to occur.

If you notice some peeling and reddening of the skin during the first weeks of using SOLUGEL®, stop using the product for one to two days.

If you experience severe skin irritation (redness, dryness, itching, stinging/burning feeling, discontinue use and consult your doctor.

Do not use too much SOLUGEL® or use it more often than prescribed, as this will not help your acne clear up more quickly and may cause skin irritation.

SOLUGEL® can make your skin more sensitive to the harmful effects of the sun. Avoid the use of sunbeds and sunlamps and minimise the time you spend in the sun. You should use a sunscreen and wear protective clothing while using SOLUGEL®.

SOLUGEL® may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

INTERACTIONS WITH THIS MEDICATION

Some medicines can affect how SOLUGEL® works, or make it more likely that you'll have side effects such as redness, peeling and skin irritation.
These include:

- acne medicines that are applied to the skin which contain tretinoin, isotretinoin or tazarotene
- some other acne medicines that are applied to the skin.

Applying SOLUGEL® at the same time as sulphonamide-containing medicines such as dapsone and sulfacetamide can cause a temporary discoloration of skin or facial hair (yellow/orange colour).

Tell your doctor or pharmacist if you are taking any of these medications.

PROPER USE OF THIS MEDICATION

Always use SOLUGEL® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use SOLUGEL® for as long as your doctor or pharmacist recommends. It is important to continue to use this medicine until the acne has gone. If you stop too soon, your acne may return.

If you experience skin irritation (dryness or peeling) while using SOLUGEL®, your doctor may reduce the amount of times you use SOLUGEL® or may temporarily stop use of SOLUGEL® for a short time and then start again.

Usual dose (adults and children 12 years of age and older):

Use once or twice daily, or as directed by your doctor. Because drying of the skin may occur, begin with one application daily, and then gradually increase to two applications daily, if needed.

1. Wash your hands and the affected area using non-medicated soap (contains no benzoyl peroxide) and gently dry, before use.
2. Put a thin film of SOLUGEL® on the entire affected skin area, using your fingertips, and smooth in.
3. Wash your hands after using SOLUGEL®.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you apply too much SOLUGEL® your skin might become very irritated. If this happens stop using SOLUGEL® and contact your doctor.

The ingredients of SOLUGEL® are not expected to be harmful if swallowed in the small amounts normally applied to the face. However, if you do accidentally get a larger amount of SOLUGEL® in your mouth, rinse immediately with plenty of water and contact your doctor or pharmacist for advice.

Missed Dose:
If you forget to use SOLUGEL® apply the next dose at the usual time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, SOLUGEL® can cause side effects, but not everybody gets them.

Very Common (these may affect more than 1 in 10 people):

- Redness and peeling of the skin at the site of application.

Common (these may affect up to 1 in 10 people):

- Dryness, itching or sensitivity of the skin at the site of application.

Uncommon (these may affect up to 1 in 100 people):

- Burning sensation at the site of application

Rare (these may affect up to 1 in 1, 000 people):

- At the site of application the following may occur: discoloration of the skin, skin rash, skin allergy, other skin reactions such as irritation and pain
- Dry lips, lip swelling, and lip inflammation have been reported when SOLUGEL® was applied close to the mouth (see Warnings and Precautions).
- Photosensitivity (a skin reaction, such as a rash, that occurs after exposure to the sun or any UV light source, including a sunlamp).

Tell your doctor or pharmacist if any of the side effects listed become severe or troublesome, or if you notice any side effects not listed in this leaflet.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist immediately
		Only if severe	In all cases	
Rare	Severe allergic reaction. Signs may include raised and itchy rash (hives), swelling of the face or mouth (angioedema), causing difficulty in breathing, collapse		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking SOLUGEL®, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15º and 30ºC.

Keep out of the reach and sight of children.

Do not use SOLUGEL® after the expiry date shown on the pack.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:
- **Fax toll-free to 1-866-678-6789, or**
- **Mail to: Canada Vigilance Program**
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full prescribing information, prepared for health professionals can be found at:
or by contacting the sponsor,
GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
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1-800-387-7374

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