**Dapsone gel 5%**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**INDICATIONS AND USAGE**

Dapsone gel, 5% is indicated for the topical treatment of acne vulgaris.

**CONTRAINDICATIONS**

- Hypersensitivity to dapsone.

**WARNINGS AND PRECAUTIONS**

- Methemoglobinemia:
  - Methemoglobinemia has been identified during postmarketing use of dapsone gel, 5%. Some subjects with G6PD deficiency may also be at increased risk for methemoglobinemia.
  - Methemoglobinemia has been identified in drug-naive patients treated with dapsone gel.
  - Methemoglobinemia occurs rarely in drug-naive patients treated with dapsone gel.

- Drug Interactions with Oral Dapsone:
  - Trimethoprim-Sulfamethoxazole:
    - Increases the level of dapsone and its metabolites in the presence of TMP/SMX.
    - Levels of dapsone and its metabolites increased in the presence of TMP/SMX.

**ADVERSE REACTIONS**

- Topical Use:
  - Mild to moderate erythema was the most common adverse reaction reported (4.5% of subjects treated with dapsone gel, 5% vs. 1.6% of vehicle) with development of hyperpigmentation in 0.4% of subjects treated with dapsone gel, 5% vs. 0% of vehicle.

**ADVERSE REACTIONS (non-drug related)**

- Headache, upper respiratory tract infection, and sinusitis were reported in clinical studies with dapsone gel, 5% in subjects with acne vulgaris.

**CLINICAL STABILIZATION AND ANXIETY**

- Dapsone gel, 5% can cause skin irritation, pruritus, and erythema. These adverse reactions may be reduced by using a lower strength of dapsone gel.

**FULL PRESCRIBING INFORMATION**

**INDICATIONS AND USAGE**

Dapsone gel, 5% is indicated for the topical treatment of acne vulgaris.

**CONTRAINDICATIONS**

- Hypersensitivity to dapsone.

**WARNINGS AND PRECAUTIONS**

- Methemoglobinemia:
  - Methemoglobinemia has been identified during postmarketing use of dapsone gel, 5%. Some subjects with G6PD deficiency may also be at increased risk for methemoglobinemia.
  - Methemoglobinemia occurs rarely in drug-naive patients treated with dapsone gel.

**ADVERSE REACTIONS**

- Topical Use:
  - Mild to moderate erythema was the most common adverse reaction reported (4.5% of subjects treated with dapsone gel, 5% vs. 1.6% of vehicle) with development of hyperpigmentation in 0.4% of subjects treated with dapsone gel, 5% vs. 0% of vehicle.

**ADVERSE REACTIONS (non-drug related)**

- Headache, upper respiratory tract infection, and sinusitis were reported in clinical studies with dapsone gel, 5% in subjects with acne vulgaris.

**CLINICAL STABILIZATION AND ANXIETY**

- Dapsone gel, 5% can cause skin irritation, pruritus, and erythema. These adverse reactions may be reduced by using a lower strength of dapsone gel.
What are the possible side effects of dapsone gel, 5%?

Dapsone gel, 5% is a topical medication that can cause side effects. Common side effects include:

- Oiliness
- Peeling
- Dryness
- Redness of the skin being treated

Less common side effects may include:

- Rash
- Headache
- Nausea
- Dizziness
- Blurred vision

Some patients may experience more severe side effects, including:

- Anemia
- Methemoglobinemia
- Photosensitivity

It is important to report any side effects to your healthcare provider.

How do I use dapsone gel, 5%?

Dapsone gel, 5% is applied topically to the skin. Use a small amount (about the size of a pea) once or twice daily on the affected areas. Apply the gel according to the directions provided by your healthcare provider. If you have any questions about how to use dapsone gel, 5%, ask your pharmacist or healthcare provider.

What is the proper storage method for dapsone gel, 5%?

Dapsone gel, 5% should be stored at room temperature (68ºF to 77ºF or 20ºC to 25ºC) and away from light. Do not store in the bathroom, near a sink, or in the kitchen. Keep the bottle tightly closed when not in use.

Are there any special considerations for using dapsone gel, 5% during pregnancy?

Dapsone gel, 5% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women who are pregnant or planning to become pregnant should not use dapsone gel, 5% without first consulting their healthcare provider.

Is dapsone gel, 5% safe for use by children?

Dapsone gel, 5% is not recommended for use in children under the age of 12 years. More studies are needed to determine its safety and effectiveness in this population.

Is dapsone gel, 5% safe for use by older adults?

Clinical studies of dapsone gel, 5% did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. However, since dapsone gel, 5% is generally well-tolerated, it may be used with caution in older adults.

Is dapsone gel, 5% safe for use by women who are breastfeeding?

Dapsone gel, 5% is not recommended for use by women who are breastfeeding. Women who are breastfeeding should not use dapsone gel, 5% without first consulting their healthcare provider.

What are the ingredients in dapsone gel, 5%?

The active ingredient in dapsone gel, 5% is 5% dapsone, which is a medication used to treat acne vulgaris.

What are the possible skin reactions associated with using dapsone gel, 5%?

Common skin reactions associated with using dapsone gel, 5% include:

- Dry skin
- Peeling
- Redness
- Irritation

Less common skin reactions may include:

- Rash
- Blurred vision
- Headache

It is important to report any skin reactions to your healthcare provider.

Can you provide some examples of the laboratory results from the clinical studies?

In the clinical studies, several laboratory results were monitored. These included:

- Hemoglobin levels
- Bilirubin levels
- Haptoglobin levels
- Lactate dehydrogenase levels

The results showed that dapsone gel, 5% had minimal systemic absorption, with no changes from baseline in hemoglobin, bilirubin, haptoglobin, or lactate dehydrogenase levels.

What is the role of dapsone gel, 5% in the treatment of acne vulgaris?

Dapsone gel, 5% is used to treat acne vulgaris by reducing the number of Propionibacterium acnes bacteria on the skin. This helps to reduce inflammation and improve the appearance of acne.

Can dapsone gel, 5% be used for other conditions?

Dapsone gel, 5% is specifically intended for use in the treatment of acne vulgaris and should not be used for other conditions without the guidance of a healthcare provider.

Has dapsone gel, 5% been studied in children or elderly populations?

Dapsone gel, 5% is not recommended for use in children under the age of 12 years. More studies are needed to determine its safety and effectiveness in this population. However, dapsone gel, 5% has been studied in elderly populations and has shown promising results.

Is dapsone gel, 5% safe for use in the treatment of mild acne?

Yes, dapsone gel, 5% is generally well-tolerated and safe for use in the treatment of mild acne. However, it is important to report any side effects to your healthcare provider.

Is dapsone gel, 5% effective for the treatment of severe acne?

Dapsone gel, 5% has been shown to be effective in the treatment of severe acne. However, it is important to consult with a healthcare provider to determine the best treatment option for you.

Can dapsone gel, 5% be used in combination with other acne medications?

Yes, dapsone gel, 5% can be used in combination with other acne medications. However, it is important to consult with a healthcare provider to determine the best treatment plan for you.

Has dapsone gel, 5% been studied in patients with severe acne?

Dapsone gel, 5% has been studied in patients with severe acne and has shown promising results. However, it is important to consult with a healthcare provider to determine the best treatment option for you.