

DAPTON GEL

Dapsone Gel, 7.5%

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1. What Dapton Gel is used for

Dapton Gel is a prescription medicine used on the skin (topical) to treat acne in people 12 years and older.

DAPTON GEL has not been studied in children under 12 years of age.

2. How Dapton Gel works

It works by slowing or stopping the growth of bacteria and decreasing inflammation.

3. Before you use Dapton Gel

Before you use Dapton Gel tell your doctor about all of your medical conditions, including if you:

- have a glucose-6-phosphate dehydrogenase deficiency (G6PD)
- have higher than normal levels of methemoglobin in your blood (methemoglobinemia)
- are pregnant or plan to become pregnant. It is not known if Dapton Gel will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Dapton Gel can pass into your breast milk and may harm your baby. You and your doctor should decide if you will use Dapton Gel or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially, tell your doctor if you are using acne medicines that contain benzoyl peroxide. Use of benzoyl peroxide with Dapton Gel at the

same time may cause your skin or facial hair to temporarily turn yellow or orange at the site of application.

Warnings and precautions

Hematological Effects

Methemoglobinemia

Cases of methemoglobinemia, with resultant hospitalization, have been reported post-marketing in association with twice daily Dapton Gel treatment.

Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methemoglobinemia are most susceptible to drug induced methemoglobinemia. Avoid use of Dapton Gel in those patients with congenital or idiopathic methemoglobinemia.

Signs and symptoms of methemoglobinemia may be delayed some hours after exposure. Initial signs and symptoms of methemoglobinemia are characterized by a slate grey cyanosis seen in, e.g., buccal mucous membranes, lips, and nail beds. Advise patients to discontinue Dapton Gel and seek immediate medical attention in the event of cyanosis.

Dapton Gel can cause elevated methemoglobin levels particularly in conjunction with methemoglobin-including agents.

Hemolysis

Oral Dapsone treatment has produced dose-related hemolysis and hemolytic anemia. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more prone to hemolysis with the use of certain drugs. G6PD deficiency is most prevalent in populations of African, South Asian, Middle Eastern, and Mediterranean ancestry.

In clinical trials, there was no evidence of clinically relevant hemolysis of hemolytic anemia in subjects treated with topical Dapsone. Some subjects with G6PD deficiency using Dapsone Gel 5%, twice daily developed laboratory changes suggestive of

hemolysis.

Discontinue Dapton Gel 7.5%, if signs and symptoms suggestive of hemolytic anemia occur. Avoid use of Dapton Gel in patients who are taking oral Dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of Dapton Gel with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

Peripheral Neuropathy

Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral Dapsone treatment. No events of peripheral neuropathy were observed in clinical trials with topical Dapton Gel treatment.

Skin Reactions

Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral Dapsone treatment. These types of skin reactions were not observed in clinical trials with topical Dapsone treatment.

4. How to use Dapton Gel

- Use Dapton Gel exactly as your doctor tells you to use it.
- Apply Dapton Gel one time a day.
- Gently wash and pat dry the areas of your skin where you will apply Dapton Gel.
- Apply a pea-sized amount of Dapton Gel in a thin layer to the entire face. A thin layer may also be applied to other affected areas as instructed by your doctor.
- Rub Dapton Gel gently and completely.
- Wash your hands after applying Dapton Gel.
- If your acne does not get better after using Dapton Gel for 12 weeks, talk to your doctor about continuing treatment.

5. Side effects

Dapton Gel may cause serious side effects, including:

Decrease of oxygen in your blood caused by a certain type of abnormal red blood cell (methemoglobinemia).

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Stop using Dapton Gel and get medical help right away if your lips, nail beds, or the inside of your mouth turns grey or blue.

Breakdown of red blood cells (hemolytic anemia). Some people with G6PD deficiency using Dapton Gel may develop mild hemolytic anemia. Stop using Dapton Gel and tell your doctor right away if you get any of the following signs and symptoms:

- back pain
- shortness of breath
- tiredness or weakness
- dark brown urine
- fever
- yellow or pale skin

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

6. Storage and Disposal of Dapton Gel

- Storage

Store below 30°C.

Protect from Freezing.

Keep this medicine out of reach of children.

Do not use this medicine after the expiry date which is stated on carton after EXP. The Expiry date refers to the last day of that month.

7. Product Description

- What it looks like

Description: Off-white to yellow color homogeneous gel with suspended particles, no phase separation and sedimentation, free of lumps and foreign matter.

- Ingredients

- Active ingredient

Each gram of gel contains:

Dapsone USP

- Inactive ingredients

- Diethylene Glycol Monoethyl Ether (Transcutol P)
- Carbomer Homopolymer Type C (Carbopol 980)
- Methyl Paraben
- Sodium Hydroxide
- Purified water

MAL Number:

MAL25036128ACZ

8. Manufacturer

Encube Ethicals Pvt. Ltd.
Madkaim, Ponda, Goa – 403404,
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Product Registration Holder

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9. Date of Revision

20.08.2024

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