Betamethasone Dipropionate Cream USP, 0.05%  
(Strength expressed as betamethasone)

**Contraindications**

- Hypersensitivity to any component of this medicine.

**Warnings and Precautions**

- Effects on endocrine system: Betamethasone dipropionate cream (augmented) can cause reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of treatment. Risk factors include the use of high-potency topical corticosteroids, use over a large treatment area or for extended periods, use in elderly patients, use in patients with a weakened immune system, or concurrent use of other corticosteroids.

**Adverse Reactions**

- The most common adverse reactions reported in 0.4% of adult patients include: skin atrophy, telangiectasia, bruising, shiners.

**Pharmacodynamic**

- 12.2 Pharmacodynamics

**Pharmacokinetics**

- 12.3 Pharmacokinetics

**Nonclinical Toxicology**

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

**Clinical Pharmacology**

- 14 Clinical Pharmacology

**How Supplied/Storage and Handling**

- 16 How Supplied/Storage and Handling

**Patient Counseling Information**

- 17 Patient Counseling Information

**Full Prescribing Information**

- 30 Full Prescribing Information

**Dose and Administration**

- 2.1 Dose and Administration

**Indications and Usage**

- 2.2 Indications and Usage

**Dose Forms and Strengths**

- 3.1 Dose Forms and Strengths

**Contraindications**

- 4.1 Contraindications

**Warnings and Precautions**

- 5.1 Warnings and Precautions

**Adverse Reactions**

- 6.1 Adverse Reactions

**Use in Specific Populations**

- 7.1 Use in Specific Populations

**Pediatric Use**

- 8.4 Pediatric Use

**Geriatric Use**

- 8.5 Geriatric Use

**Pregnancy**

- 8.1 Pregnancy

**Lactation**

- 8.2 Lactation

**Use in Specific Populations**

- 8.3 Use in Specific Populations

**Pediatric Use**

- 10 Use in Pediatric Patients

**Carcinogenesis, Mutagenesis**

- 11.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

**Impairment of Fertility**

- 11.2 Impairment of Fertility

**Mutagenesis**

- 11.3 Mutagenesis

**Impairment of Fertility**

- 11.4 Impairment of Fertility

**Carcinogenesis**

- 11.5 Carcinogenesis

**Adverse Reactions**

- 12.1 Adverse Reactions

**Pharmacodynamics**

- 12.2 Pharmacodynamics

**Pharmacokinetics**

- 12.3 Pharmacokinetics

**Carcinogenesis**

- 13.1 Carcinogenesis

**Mutagenesis**

- 13.2 Mutagenesis

**Impairment of Fertility**

- 13.3 Impairment of Fertility

**FDA Approval History**

- 16.1 FDA Approval History

**Before Using Betamethasone Dipropionate Cream**

- 17.1 Before Using Betamethasone Dipropionate Cream

**Patient Information**

- 17.2 Patient Information

**Full Prescribing Information**

- 30 Full Prescribing Information

**Dose and Administration**

- 2.1 Dose and Administration

**Indications and Usage**

- 2.2 Indications and Usage

**Dose Forms and Strengths**

- 3.1 Dose Forms and Strengths

**Contraindications**

- 4.1 Contraindications

**Warnings and Precautions**

- 5.1 Warnings and Precautions

**Adverse Reactions**

- 6.1 Adverse Reactions

**Use in Specific Populations**

- 7.1 Use in Specific Populations

**Pediatric Use**

- 8.4 Pediatric Use

**Geriatric Use**

- 8.5 Geriatric Use

**Pregnancy**

- 8.1 Pregnancy

**Lactation**

- 8.2 Lactation

**Use in Specific Populations**

- 8.3 Use in Specific Populations

**Pediatric Use**

- 10 Use in Pediatric Patients

**Carcinogenesis, Mutagenesis**

- 11.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

**Impairment of Fertility**

- 11.2 Impairment of Fertility

**Mutagenesis**

- 11.3 Mutagenesis

**Impairment of Fertility**

- 11.4 Impairment of Fertility

**Carcinogenesis**

- 13.1 Carcinogenesis
How should I use Betamethasone Dipropionate Cream (Augmented)?

Use betamethasone dipropionate cream (augmented) exactly as your healthcare provider tells you to use it. Be sure to use it the same way each time. Do not use more or less than the amount prescribed by your healthcare provider.

1. Clean the area where you are going to apply the cream. If you are using the cream to treat diaper rash or redness, wash the diaper or clothing that covers the area with soap and water. If you are using the cream to treat the skin on your face, wash it with soap and water. Avoid using baby powder on the skin before you apply the cream.

2. Apply a thin layer (film) of betamethasone dipropionate cream (augmented) to the affected skin area 1 or 2 times each day. Do not apply more than 50 grams of betamethasone dipropionate cream (augmented) in 1 week.

3. Avoid bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.

4. Wash your hands after applying betamethasone dipropionate cream (augmented) unless you are using the medicine to treat an infection of the eye.

What are the possible side effects of Betamethasone Dipropionate Cream (Augmented)?

Betamethasone Dipropionate Cream (Augmented) may cause serious side effects, including:

- Systemic effects: thinning of the skin, changes in the growth and weight of children, redness of the skin.
- Adrenal gland problems: suppression of the adrenal gland, suppression of the immune system, increased risk of infections, decreased ability to fight infections.
- Hypertension: increased blood pressure, increased heart rate, increased risk of heart attack or stroke.
- Diabetes: increased blood sugar, decreased appetite, increased thirst, increased urination, blurred vision.
- Other side effects: pain at the injection site, allergic reactions, local reactions such as redness, swelling, burning, or itching.

If you experience any of these side effects, stop using the cream and call your healthcare provider immediately.

How should I store Betamethasone Dipropionate Cream (Augmented)?

Store the cream at room temperature between 68°F to 77°F (20°C to 25°C). Protect from freezing.

Keep betamethasone dipropionate cream (augmented) and all medicines out of the reach of children.

General information about the safe and effective use of Betamethasone Dipropionate Cream (Augmented).

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use betamethasone dipropionate cream (augmented) for conditions other than those listed in this leaflet unless directed by your healthcare provider.

What are the ingredients in Betamethasone Dipropionate Cream (Augmented)?

Active ingredients:

- Betamethasone dipropionate (0.05%)

Inactive ingredients:

- Carbomer homopolymer type C
- Ceteareth-30
- Chloroform
- Cyclomethicone
- Glycerin
- Petrolatum
- Propylene glycol
- Purified water
- Stearic acid
- Sorbitan solution
- White petrolatum
- White wax

Manufactured by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1

Distributed by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532

Revised: December 2020 5212541 53

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 12/2020