

Brand Name : AGOMETHASONE TABLETS	2021
Generic Name : Dexamethasone Tablets BP 0.5 mg	
Module 1	Administrative Information and Product Information
1.5	Product Information
Confidential	

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGOMETHASONE TABLETS (Dexamethasone Tablets BP 0.5 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Dexamethasone BP 0.5 mg

3. Pharmaceutical form:

White, elongated, flat, uncoated tablet having embossed 'AGOG' on one side and a breakline on other side of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Dexamethasone is a glucocorticoid medication used to treat rheumatic problems, a number of skin diseases, severe allergies, asthma, chronic obstructive lung disease, croup, brain swelling, eye pain following eye surgery, and along with antibiotics in tuberculosis. In adrenocortical insufficiency, it may be used in combination with a mineralocorticoid medication such as fludrocortisone. In preterm labor, it may be used to improve outcomes in the baby. It may be given by mouth, as an injection into a muscle, as an injection into a vein, as a topical cream or ointment for the skin or as a topical ophthalmic solution to the eye. The effects of dexamethasone are frequently seen within a day and last for about three days.



AGOG Pharma Ltd.



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, Vasai (E), Dist. Thane - 401 208, INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

4.2 Posology and Method of Administration:

All possible dosages and forms may not be included here. Your dose, form, and how often you take it will depend on:

- your age
- the condition being treated
- how severe your condition is
- other medical conditions you have
- how you react to the first dose

Dosage for inflammation and other conditions

Generic: Dexamethasone

- **Form:** oral tablet
- **Strengths:** 0.5 mg, 0.75 mg, 1 mg, 1.5 mg, 4 mg, and 6 mg

Brand: DexPak

- **Form:** oral tablet
- **Strengths:** 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, 1.5 mg, 4 mg, and 6 mg

Adult dosage (ages 18 years and older)

Typical dosage: 0.75–9 mg every day, depending on the condition being treated.

Child dosage (ages 0–17 years)

Initial dosage: 0.02–0.3 mg per kilogram of body weight per day, taken in three or four divided doses. Dosage depends on the condition being treated.



Senior dosage (ages 65 years and older)

The kidneys and liver of older adults may not work as well as they used to. This can cause your body to process drugs more slowly. As a result, more of a drug stays in your body for a longer time. This raises your risk of side effects.

Your doctor may start you on a lowered dose or a different dosing schedule. This can help keep levels of this drug from building up too much in your body.

Special dosage considerations

When stopping treatment, your dosage should be decreased slowly over time. This helps to prevent withdrawal side effects.

Disclaimer: Our goal is to provide you with the most relevant and current information. However, because drugs affect each person differently, we cannot guarantee that this list includes all possible dosages. This information is not a substitute for medical advice. Always speak with your doctor or pharmacist about dosages that are right for you.

Method of administration: Oral.

4.3 Contraindications:

Contraindications of dexamethasone include, but are not limited to:

- Uncontrolled infections
- Known hypersensitivity to dexamethasone
- Cerebral malaria
- Systemic fungal infection
- Concurrent treatment with live virus vaccines (including smallpox vaccine)

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:



5.2 Pharmacodynamic Properties:

Corticosteroids bind to the glucocorticoid receptor, inhibiting pro-inflammatory signals, and promoting anti-inflammatory signals. Dexamethasone's duration of action varies depending on the route. Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces. Patients taking corticosteroids should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Di Basic Calcium Phosphate	BP
Maize starch	BP
Sodium Lauryl Sulphate	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Purified talc	BP
Magnesium stearate	BP

6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:

1000 tablets packed in one Jar and 10 tablets packed in one Blister

6.6 Special precautions for disposal:

None reported.

7. Registrant:

AGOG PHARMA LTD.

Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauripada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:

AGOG PHARMA LTD.



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9. Date of revision of the text :

1.5.2 Container labelling

LABEL

Not applicable