WARNINGS AND PRECAUTIONS

WARNING, When used for asthma, budesonide inhalation suspension is not indicated for the relief of acute bronchospasm. (1.1)

5.1 Local Effects

Mouth Ulceration

• When using budesonide inhalation suspension, patients may develop mouth ulceration. If severe, the ulceration may require treatment with appropriate medicine. (5.1)

• In adults treated with budesonide inhalation suspension, the incidence of mouth ulceration was observed in 24-27% of patients. (5.1)

• In children treated with budesonide inhalation suspension, the incidence of mouth ulceration was less than 1. (5.1)

5.2 Systemic Effects

• In adult patients treated with budesonide inhalation suspension, the effects on the HPA axis have been observed following systemic corticosteroids therapy. These events usually, but not always, resolve following discontinuation of therapy. (5.2)

5.3 Hypersensitivity Reactions Including Anaphylaxis

• Hypersensitivity reactions, including anaphylaxis, have been observed in adult patients treated with budesonide inhalation suspension. Discontinue budesonide inhalation suspension and institute appropriate therapy. (5.3)

5.4 Immunomodulatory Effects

• Budesonide inhalation suspension may suppress the immune system and may increase the risk of developing infections. Patients treated with systemic corticosteroids are at increased risk of developing bacterial, viral, fungal, or other infections. (5.4)

5.5 Reduced Growth Velocity

• Infants and children treated with budesonide inhalation suspension who are on drugs that suppress the immune system should be monitored closely for growth related problems. (5.5)

5.6 Adrenal Suppression

• Adrenal suppression may occur with very high doses of systemic corticosteroids or with long-term systemic corticosteroid therapy. Such infants should be monitored closely for signs of hypoadrenalism when systemic corticosteroids are withdrawn. (5.6)

5.7 Reduction in Bone Mineral Density

• Decreases in bone mineral density (BMD) have been observed in adult patients treated with high doses of systemic corticosteroids, including budesonide. (5.7)

5.8 Effects on Growth

• Budesonide inhalation suspension may cause a reduction in growth velocity in children treated with systemic corticosteroids. (5.8)

5.9 Glaucoma and Cataracts

• The effects on glaucoma and cataracts have been observed in adult patients treated with budesonide inhalation suspension. (5.9)

5.11 Oral Candidiasis

• Oral candidiasis has been observed in adult and pediatric patients treated with budesonide inhalation suspension. (5.11)

5.12 Decrease in Pup Weight

• Decreased pup weights, and skeletal abnormalities have been observed in rats and rabbits following exposure to budesonide. (5.12)

5.13 Implantation Rates

• Implantation rates were decreased in rats following exposure to budesonide. (5.13)

5.14 Clinical Pharmacology

• Oral corticosteroids, including budesonide, are metabolized in the liver by the CYP3A4 pathway. (5.14)

5.16 Pregnancy

• Use budesonide inhalation suspension in pregnant women only if the benefit outweighs the risk. (5.16)

5.17 Lactation

• Nursing mothers should be instructed not to breastfeed while using budesonide inhalation suspension. (5.17)

5.18 Children

• Use budesonide inhalation suspension exactly as prescribed. (5.18)

5.20 Administration

• Use budesonide inhalation suspension with a jet nebulizer. (5.20)

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

• Budesonide, a glucocorticoid, is via cytochrome P450 (CYP) isoenzyme 3A4 metabolism. (12.1)

12.2 Animal Data

• Teratogenicity: Budesonide has been shown to be embryocidal in rabbits and rats. Budesonide produced fetal loss, decreases in fetal body weight, and occasionally fetal skeletal abnormalities in rabbits and rats. (12.2)

12.3 Clinical Studies

• In adult patients with asthma treated with budesonide inhalation suspension, improvement in asthma control was observed in at least 35% of cases. (12.3)

12.4 Children

• In children treated with budesonide inhalation suspension, improvement in asthma control was observed in at least 35% of cases. (12.4)

12.5 Pregnancy

• Budesonide inhalation suspension is not indicated for the relief of acute bronchospasm. (12.5)

12.6 Lactation

• Nursing mothers should be instructed not to breastfeed while using budesonide inhalation suspension. (12.6)

12.7 Administration

• Use budesonide inhalation suspension with a jet nebulizer. (12.7)

17 SIDE EFFECTS

17.1 Oral Candidiasis

• Oral candidiasis has been observed in adult and pediatric patients treated with budesonide inhalation suspension. (17.1)

17.2 Oral Ulceration

• Oral ulceration has been observed in adult and pediatric patients treated with budesonide inhalation suspension. (17.2)

17.3 Glaucoma

• Glaucoma has been observed in adult patients treated with budesonide inhalation suspension. (17.3)

17.4 Cataracts

• Cataracts have been observed in adult patients treated with budesonide inhalation suspension. (17.4)

17.8 Reduced Growth Velocity

• Reduced growth velocity has been observed in children treated with budesonide inhalation suspension. (17.8)

17.11 FDA-Approved Patient Labeling

• A Patient Medication Guide should be provided to patients. (17.11)

17.12 Concomitant Use with Other Medications

• Concurrent use of systemic corticosteroids is associated with increased effects on the HPA axis. (17.12)

17.13 Adverse Reactions

• The most common adverse reactions observed with budesonide inhalation suspension are listed below. All adverse reactions have been observed in the clinical trials. (17.13)

• The incidence of adverse reactions observed in clinical trials is listed below. All adverse reactions have been observed in the clinical trials. (17.13)

17.14 Population-Specific Studies

• Adverse Events

17.15 Other Important Information

• In adult patients treated with budesonide inhalation suspension, the adverse events observed were listed below. All adverse reactions have been observed in the clinical trials. (17.15)

• In children treated with budesonide inhalation suspension, the adverse events observed were listed below. All adverse reactions have been observed in the clinical trials. (17.15)

17.16 Other Drugs

• Budesonide inhalation suspension is metabolized in the liver by the CYP3A4 pathway. (17.16)

17.17 Idiosyncratic Reactions

• Idiosyncratic reactions have been observed in adult patients treated with budesonide inhalation suspension. (17.17)

17.18 Other Important Information

• In adult patients treated with budesonide inhalation suspension, the adverse events observed were listed below. All adverse reactions have been observed in the clinical trials. (17.18)

• In children treated with budesonide inhalation suspension, the adverse events observed were listed below. All adverse reactions have been observed in the clinical trials. (17.18)

17.19 Other Important Information

• In adult patients treated with budesonide inhalation suspension, the adverse events observed were listed below. All adverse reactions have been observed in the clinical trials. (17.19)

• In children treated with budesonide inhalation suspension, the adverse events observed were listed below. All adverse reactions have been observed in the clinical trials. (17.19)
1. Pharmacokinetics

Budesonide is a corticosteroid that is rapidly absorbed following inhalation. Its systemic availability after inhalation is approximately 1% to 2%. In adults and children 12 months to 8 years of age on a mcg/m

2. Precautions

Hepatic Insufficiency: There is no experience with budesonide inhalation suspension in patients with hepatic insufficiency. If such patients require treatment, use the lowest effective dose and monitor closely for signs of adrenal insufficiency.

3. Adverse Reactions

The most common adverse reactions associated with budesonide inhalation suspension are cough, throat irritation, and oral candidiasis. These reactions are usually mild to moderate in severity and rarely require discontinuation of therapy. Other adverse reactions include nasal irritation, hoarseness, and oral ulceration.

4. Administration and Dosage

Budesonide inhalation suspension should be administered by the patient or caregiver using a metered dose inhaler with a tube spacer to 1400 mcg of oral budesonide. The dose should be individualized based on the patient's response and clinical symptoms.

5. Overdosage

Overdosage of budesonide inhalation suspension is unlikely to occur because of its aerosol formulation. However, if an overdose is suspected, the patient should be monitored closely for signs of systemic corticosteroid toxicity.

6. Pediatric Use

Budesonide inhalation suspension is indicated for the management of persistent asthma in pediatric patients 6 months to 8 years of age. The recommended dose is 1 mg twice daily, with a maximum of 4 mg per day.

7. Contraindications

Budesonide inhalation suspension is contraindicated in patients with a history of hypersensitivity to any component of the formulation.

8. NDC Numbers

NDC 0487-9701-01 0.5 mg/2 mL
NDC 0487-9701-30 0.5 mg/2 mL

9. How Supplied / Storage and Handling

Budesonide inhalation suspension is supplied in single-dose ampules in a carton. Each single-dose ampule contains 2 mL of budesonide inhalation suspension that is written for health information about budesonide inhalation suspension if you would like more medical information about budesonide inhalation suspension.

10. Patient Counseling Information

Instruct the patient in the proper technique for use of the inhalation device and advise the patient to avoid getting medication in the eyes.

11. Description

Budesonide inhalation suspension is a white to light yellowish-white suspension containing 200 mcg of budesonide per metered actuation. The inhalation suspension contains active ingredient: budesonide, inactive ingredients: citric acid, edetate disodium dihydrate, polysorbate 80, sodium chloride, sodium citrate, and water for injection.

12. Clinitest

Place 1 mL of Clinitest solution in a test tube. Add 3 drops of budesonide inhalation suspension. Mix well. Place the test tube in a water bath at 37ºC (98.6ºF) and observe for color change. No color change is expected.

13. Emergency Information

In case of overdose, symptoms may include dizziness, weakness, fatigue, hypotension, and bradycardia. Treatment includes supportive care and monitoring of vital signs.

14. Stability

Store at room temperature 20 to 25ºC (68 to 77ºF) and away from light. Do not freeze. Protect from light until ready to use.

15. Cross-Reactivity

There is no known cross-reactivity between budesonide and other corticosteroids. However, patients with a history of sensitivity to corticosteroids may react to budesonide.

16. Incompatibilities

Incompatible with budesonide inhalation suspension.

17. 17   HOW SUPPLIED / STORAGE AND HANDLING

Budesonide inhalation suspension should be used with a metered dose inhaler with a tube spacer. The device should be used in the upright position at 20 to 25ºC (68 to 77ºF) [see USP 20].

18. 17.4   Hypersensitivity including Anaphylaxis

Onset of action on the respiratory tract.

19. 17.5   Cimetidine

Ketoconazole: a strong inhibitor of cytochrome

20. 17.6   Interaction of Corticosteroid and Beta-

agonist such as albuterol.