1.1 Mild to Moderate Active Crohn's Disease

- Maintenance of clinical remission of mild to moderate active Crohn's disease
- Treatment of mild to moderate active Crohn's disease

3. DOSAGE FORMS AND STRENGTHS

- Budesonide 3 mg capsules are hard gelatin capsules with an opaque light yellow cap and light yellow, opaque, light orange body. Each capsule contains 3 mg of budesonide. The recommended adult dosage for the treatment of mild to moderate active Crohn's disease is 9 mg/day (total daily dose) of budesonide. This is a glucocorticosteroid, general warnings concerning glucocorticosteroid-associated adverse reactions should be observed.

7. ADVERSE REACTIONS

- Ear infection—not otherwise specified, bronchitis, rhinitis, sinusitis, asthma, arthralgia, arthritis.

14. CLINICAL STUDIES

- In clinical trials (52 weeks). A total of 145 patients were treated with budesonide 9 mg (total daily dose). The most common adverse reactions were nausea and abdominal pain, both occurring in patients treated with budesonide 9 mg (total daily dose) and placebo. In patients treated with budesonide 9 mg (total daily dose) and placebo, clinical trials (52 weeks) have been completed to date, adverse reactions were observed to be benign and not considered to be related to drug therapy. In patients treated with budesonide 9 mg (total daily dose), adverse reactions were observed to be benign and not considered to be related to drug therapy. In patients treated with budesonide 9 mg (total daily dose), adverse reactions were observed to be benign and not considered to be related to drug therapy. In patients treated with budesonide 9 mg (total daily dose), adverse reactions were observed to be benign and not considered to be related to drug therapy.
How should I store budesonide?

- Keep budesonide in a tightly closed container.
- Keep budesonide and all medicines out of reach from children.
- Do not store in the bathroom near a sink, but in a cool, dry place.
- Do not freeze budesonide. Avoid exposure to heat and direct sunlight.

• Do not use budesonide for a condition for which it was not prescribed. Do not give budesonide to another person, even if they have the same condition. Do not use this medicine for a different condition or for a longer time than prescribed by your healthcare provider.

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How should I use budesonide?

- Follow the instructions provided by your healthcare provider. Use budesonide exactly as directed on the label or as prescribed by your healthcare provider. Do not take more budesonide than recommended in the label or by your healthcare provider.
- Do not use budesonide for longer than recommended.
- Do not take any medication other than the one prescribed by your healthcare provider unless it is specifically instructed in your Patient Information leaflet.

• To avoid side effects, do not use budesonide for longer than necessary. Do not take more than the prescribed dose unless specifically instructed in your Patient Information leaflet.

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