Axid[™] (nizatidine) Oral Solution



PRESCRIBED for over 30 years¹

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While there are many H₂-receptor antagonist options available, some patients with an active duodenal ulcer may benefit from the **only oral liquid form of nizatidine**^{2,3}



Indicated for patients 12 years of age and older²

Available as a peppermint-flavored syrup²

Indications and Usage

In adult patients, nizatidine is indicated for:

- Up to 8 weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within 4 weeks.
- Maintenance therapy for duodenal ulcer patients at a dosage of 150 mg/daily at bedtime after healing of an active duodenal ulcer.
- Up to 12 weeks for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis, and associated heartburn due to GERD.
- Up to 8 weeks for the treatment of active benign gastric ulcer. Before initiating therapy, care should be taken to exclude the possibility of malignant gastric ulceration.

In pediatric patients ages 12 years and older, nizatidine oral solution is indicated for:

• Up to 8 weeks for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis, and associated heartburn due to GERD.

Important Safety Information

Contraindication

Nizatidine oral solution is contraindicated in patients with known hypersensitivity to the drug or with a history of hypersensitivity to other H₂-receptor antagonists.

Please see additional Important Safety Information on next page.

Please see the full Prescribing Information enclosed.

MORE 90%

OF COMMERCIALLY INSURED PATIENTS MAY PAY AS \$ 5*,4 LITTLE AS

Automatic co-pay savings with the eVoucher Rx[™] program

- No cards or coupons are needed
- Most patients with commercial insurance will receive an automatic co-pay reduction at participating pharmacies when picking up an Axid prescription
- To see a list of participating pharmacies, go to evoucherrx.relayhealth.com/storelookup

Subject to eligibility. Individual out-of-pocket costs may vary. Not valid for patients covered under Medicare, Medicaid, or other federal or state programs.

*Of commercially insured patients who filled Axid prescriptions, 90% paid a \$5 co-pay for a 30-day supply from January 2019 to December 2019.

Important Safety Information (cont'd)

Precautions

Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

Adverse Reactions (adult)

In placebo-controlled trials, anemia (0.2% vs 0%) and urticaria (0.5% vs 0.1%) were significantly more common in the nizatidine group compared to the placebo group.

The only adverse event that occurred in >10% of patients receiving nizatidine was headache. Adverse events that occurred in 3% to 10% of patients were pain, asthenia, diarrhea, dizziness, insomnia, rhinitis, and pharyngitis.

Adverse Reactions (pediatric)

In controlled clinical trials in pediatric patients (aged 2 to 18 years), adverse experiences that occurred in >5% of patients were pyrexia, nasopharyngitis, diarrhea, vomiting, irritability, nasal congestion, and cough. Most adverse events were mild or moderate in severity. Mild elevations in serum transaminase (1 to 2 ULN) were noted in some patients. Adverse reactions reported for nizatidine may also occur with nizatidine oral solution.

Use in Specific Populations

Pregnancy and Nursing Mothers: Only use nizatidine during pregnancy and while nursing if it is clearly needed.

Pediatric Use: Effectiveness in pediatric patients <12 years of age has not been established.

<u>Geriatric Use</u>: Differences in responses between the elderly and younger patients have not been identified, but greater sensitivity of some older individuals cannot be ruled out. Elderly patients are more likely to have decreased renal function. Select doses carefully and consider monitoring renal function.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Specialty, a division of Amneal Pharmaceuticals LLC at 1–877–835–5472 or the FDA at 1–800–FDA–1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information enclosed.

References: 1. US Food and Drug Administration. Drugs @FDA: FDA-approved drugs. https://www.accessdata.fda.gov/scripts/cder/daf/index. cfm?event=overview.process&AppINo=019508 Accessed February 16, 2021. 2. Nizatidine Oral Solution. Package insert. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 2019. 3. US Food and Drug Administration. *Approved Drug Products With Therapeutic Equivalence Evaluations*. 41st ed. https:// www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm Accessed February 16, 2021. 4. Data on file. Amneal Pharmaceuticals LLC.



