OMEPRAZOLE- omeprazole capsule, delayed release
Central Packaging

1.1 Treatment of Active Duodenal Ulcer

Omeprazole delayed-release capsules are indicated for short-term treatment of active duodenal ulcer in adults. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

1.2 Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence

Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

Triple Therapy

Omeprazole delayed-release capsules in combination with clarithromycin and amoxicillin, are indicated for treatment of patients with H. pylori infection and duodenal ulcer disease (active or up to 1-year history) to eradicate H. pylori in adults.

Dual Therapy

Omeprazole delayed-release capsules in combination with clarithromycin are indicated for treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori in adults.

Among patients who fail therapy, omeprazole delayed-release capsules are with clarithromycin is more likely to be associated with the development of clarithromycin resistance as compared with triple therapy. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted [see Clinical Pharmacology (12.4) and the clarithromycin prescribing information, Microbiology section].

1.3 Treatment of Active Benign Gastric Ulcer

Omeprazole delayed-release capsules are indicated for short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

1.4 Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD)

Omeprazole delayed-release capsules are indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks in patients 2 years of age and older.

1.5 Treatment of Erosive Esophagitis (EE) Due to Acid-Mediated GERD

Pediatric Patients 2 Years of Age to Adults

Omeprazole delayed-release capsules are indicated for the short-term treatment (4 to 8 weeks) of EE due to acid-mediated GERD that has been diagnosed by endoscopy in patients 2 years of age and older.

The efficacy of omeprazole delayed-release capsules used for longer than 8 weeks in patients with EE has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of EE or GERD symptoms (e.g., heartburn), additional 4 to 8 week courses of omeprazole

delayed-release capsules may be considered.

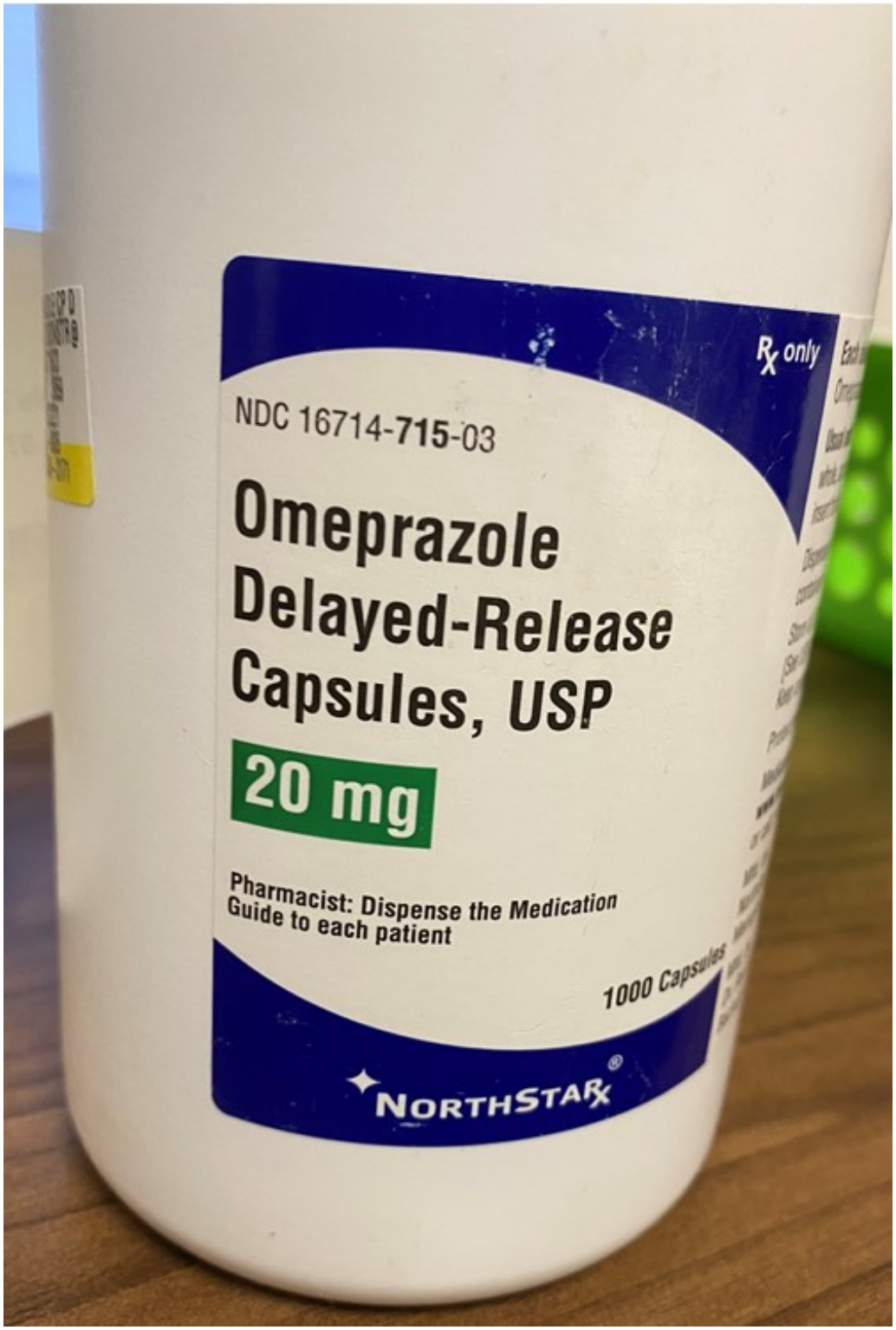
1.6 Maintenance of Healing of EE Due to Acid-Mediated GERD

Omeprazole delayed-release capsules are indicated for the maintenance healing of EE due to acid-mediated GERD in patients 2 years of age and older.

Controlled studies do not extend beyond 12 months.

1.7 Pathological Hypersecretory Conditions

Omeprazole delayed-release capsules are indicated for the long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis) in adults.



OMEPRAZOLE

omeprazole capsule, delayed release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80175-0715(NDC:16714-715)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	Omepraole;20mg;R158
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80175-0715-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075576	10/25/2019	

Labeler - Central Packaging (117617671)

Establishment

Name	Address	ID/FEI	Business Operations
Central Packaging, LLC		117617671	repack(80175-0715)

Revised: 2/2021 Central Packaging