UP AND UP OMEPRAZOLE- omeprazole tablet, delayed release Praxis, LLC

Target Corporation Omeprazole Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg

Purpose

Acid reducer

Use

- treats frequent heartburn (occurs <u>2 or more</u>days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert:

- do not use if you are allergic to omeprazole.
- omeprazole may cause severe skin reactions. Symptoms might include:
- skin reddening
- blisters
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-888-547-7400

Package/Label Principal Display Panel

Compare to Prilosec OTC ®

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

- Treats Frequent Heartburn!
- SWALLOW DO NOT CHEW

Wildberry Mint Coated Tablet

24 HR

3 Bottles Inside

Actual Size

42 Tablets

up&up ™

42 TABLETS

THREE 14-DAY COURSES OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT





UP AND UP OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-328
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZ OLE	20 mg
Inactive Ingredients		
Ingredient Name		Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARMINIC ACID (UNII: CID8Z8N95N)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
HYPROMELLOSE ACETATE SUCCINATE, UNSPECIFIED (UNII: A7ZHS2RJ34)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)		
MONOETHANOLAMINE (UNII: 5KV86114PT)		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)		
SODIUM STEARATE (UNII: QU7E2XA9TG)		
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
TRIACETIN (UNII: XHX3C3X673)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	12mm
Flavor	BERRY	Imprint Code	20
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-328- 02	3 in 1 CARTON	04/17/2015	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-328- 01	1 in 1 CARTON	03/02/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing

Application Number or Monograph Marketing Start Marketing End

Category	Citation	Date	Date
NDA	NDA022032	04/17/2015	

Labeler - Praxis, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-328) , label(59368-328) , pack(59368-328)

Revised: 1/2023

Praxis, LLC