

Proposed Labeling

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Proposed Labeling

- ◆ Dose
- ◆ Uses
- ◆ Warnings

Proposed Labeling			ZC3
	<i>NDA</i>	<i>Proposed</i>	
Dose	20 mg	10 mg	

Proposed Labeling			ZC4
	<i>NDA</i>	<i>Proposed</i>	
Dose	20 mg	10 mg	
Uses	Relief of HB	Treatment of Frequent HB	

ZC5

Proposed Labeling

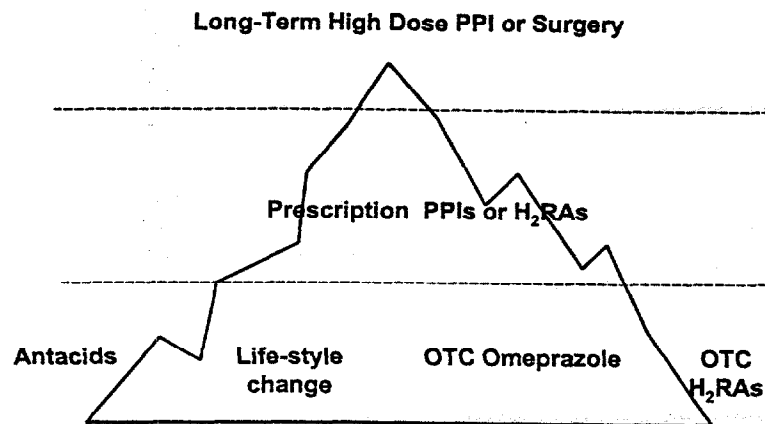
	<i>NDA</i>	<i>Proposed</i>
Dose	20 mg	10 mg
Uses	Relief of HB Prevention due to food/beverage and associated causes	Treatment of Frequent HB Prevention due to food/beverage. Only on days HB is expected

ZC6

Proposed Labeling

	<i>NDA</i>	<i>Proposed</i>
Dose	20 mg	10 mg
Uses	Relief of HB Prevention due to food/beverage and associated causes	Treatment of Frequent HB Prevention due to food/beverage. Only on days HB is expected
Warnings	Alarm symptom	Alarm symptoms Continuing/worsening symptoms Persistent use

Spectrum of Heartburn Care



Adapted from Castell D.O. *Gastroesophageal Reflux Disease: Pathogenesis, Diagnosis, Therapy*. 1985:3

Consumer Support Program

- ◆ Comprehensive heartburn education booklet
 - Explaining heartburn
 - Lifestyle modifications/Therapeutic options
 - When to see a physician
- ◆ Diverse media presentations
 - Written at 6th grade reading level
 - Booklet Available in Spanish
 - Video/dedicated Website
- ◆ Post marketing surveillance
 - 800 number on product

Summary

- ◆ Omeprazole is appropriate for the OTC management of heartburn
- ◆ Omeprazole is efficacious
- ◆ Consumers comprehend label instructions and use the product appropriately
- ◆ The product can be appropriately labeled to ensure safe and effective use
- ◆ Omeprazole is safe in the OTC setting
- ◆ The benefit of omeprazole use outweighs the potential risk

Conclusion

- ◆ 10 mg omeprazole provides a benefit to consumers

- ◆ 10 mg omeprazole can be used safely