#### RANITIDINE- ranitidine tablet RANITIDINE COOL MINT- ranitidine tablet Granules India Ltd

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Ranitidine Tablets

#### **ACTIVE INGREDIENT(S)**

Ranitidine 150 mg

#### PURPOSE

Acid reducer

#### USE(S)

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or

drinking certain foods and beverages

#### WARNINGS

Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers

#### DO NOT USE

■ if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

■ with other acid reducers

#### ASK A DOCTOR BEFORE USE IF

- had heartburn over 3 months. This may be a sign of a more serious condition.
- 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
- frequent wheezing, particularly with heartburn

- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

**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 DOCTOR IF

- your heartburn continues or worsens
- you need to take this product for more than 14 days

#### PREGNANCY/BREASTFEEDING

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.

#### DIRECTIONS

- adults and children 12 years and over:
- to **relieve** symptoms, swallow 1 tablet with a glass of water
- to **prevent** symptoms, swallow 1 tablet with a glass of water
- **30 to 60 minutes before** eating food or drinking beverages that cause heartburn
- can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- do not chew tablet (for cool mint tablets only)
- children under 12 years: ask a doctor

#### **OTHER INFORMATION**

- do not use if individual blister unit is open or torn.
- do not use if printed foil under bottle cap is open or torn
- store at 20 <sup>0</sup>-25 <sup>0</sup>C (68 <sup>0</sup>-77 <sup>0</sup>F)
- avoid excessive heat or humidity

■ this product is sodium and sugar free

### **INACTIVE INGREDIENTS**

**For 150 mg:**croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol,talcum, titanium dioxide

**For 150 mg cool mint:**acacia, croscarmellose sodium, FD&C Blue No. 1,magnesium stearate, menthol, microcrystalline cellulose,polyethylene glycol, polyvinyl alcohol, talcum, titanium dioxide

#### **Questions or comments?**

•Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM EST.

This product is not manufactured or distributed by Boehringer Ingelheim  $\ensuremath{\mathbb{R}}$  consumer health care products, distributor of Zantac 150mg and 150mg Cool Mint

#### Read the directions and warnings before use.

Keep the carton. It contains important information including tips for managing heartburn.

#### Tips for managing heartburn

- •Do not lie flat or bend over soon after eating
- •Do not eat late at night, or just before bedtime

•Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty andfried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.

- •Eat slowly and do not eat big meals
- if you are overweight, lose weight
- •if you smoke, quit smoking
- •Raise the head of your bed
- •Wear loose fitting clothing around your stomach

#### PRINCIPAL DISPLAY PANEL

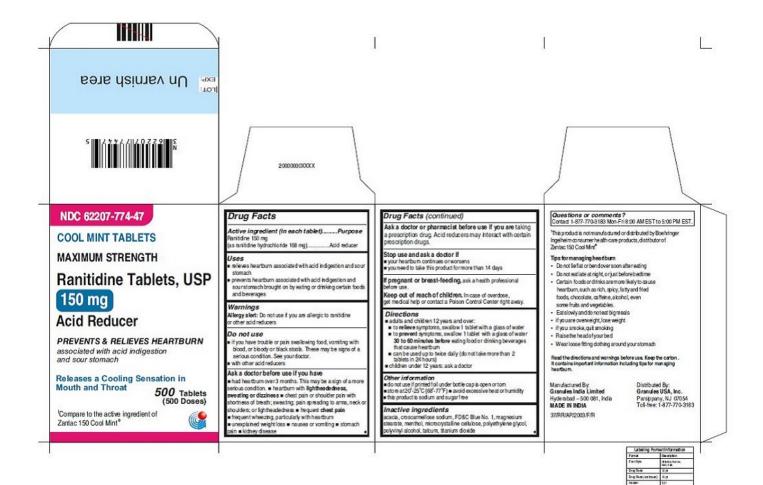
NDC 62207-774-58

"Compare to the active incredient of Zantac 150 Cod Mint"

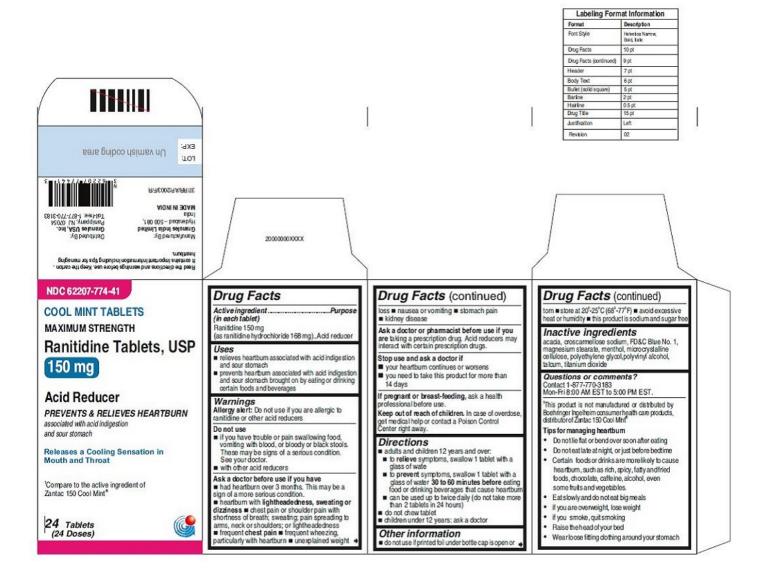
#### COOL MINT TABLETS

### Ranitidine Tablets, USP 150 mg

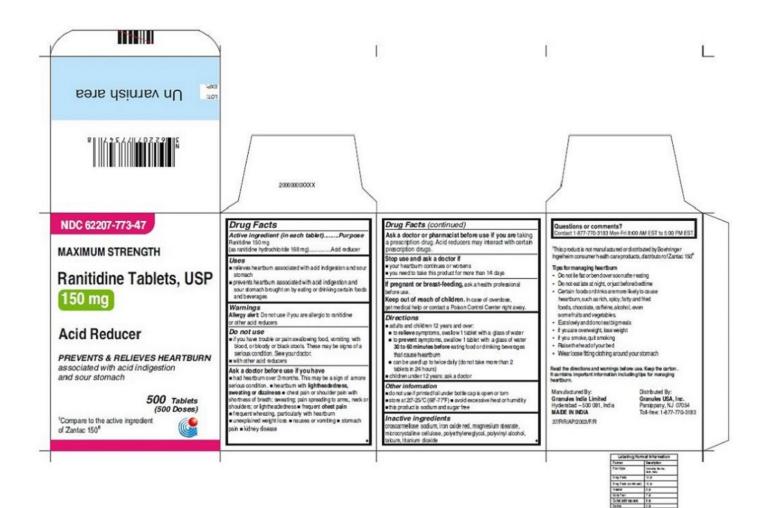


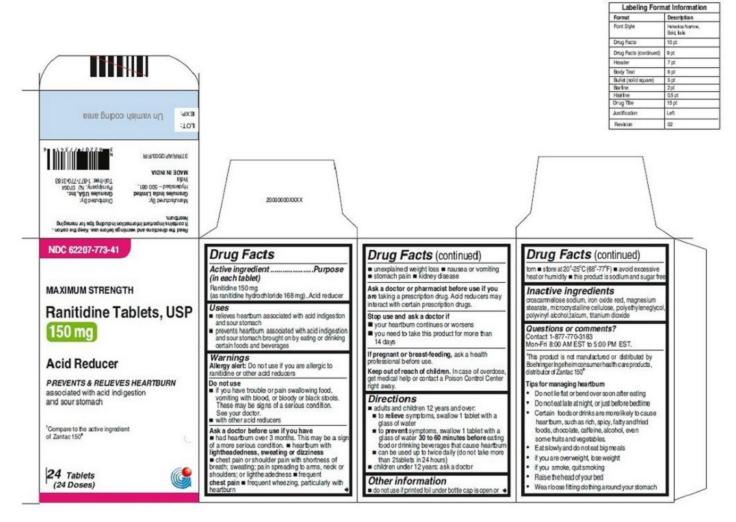


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	NDC 62207-773-58 *Compare to the active ingredient of Zantac 150 <sup>e</sup> MAXIMUM STRENGTH	area
	Acid Reducer PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach 20 (2x10) Tablets	Un Varnish area
	Drug Facts         brought on by eating or drinking certain foods and beverages           Active ingredient (in each tablet)Purpose Ranildine 150 mg (as antidine hydochloride 168 mg)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Distributed By: Granules USA, Inc. Farsippany, NJ 07054 Tol-kee: 1-377-770-3183 37/RRI AP/2000/F/R	Drug Facts (continued)         Are adoctor before use if you have serves conditor. Insurtum with ight-seedefores, serves conditor. Insurtum with ight-seedefores, serves conditor. Insurtum with ight-seedefores, serves conditor. Insurtum with ight-seedefores, serves conditor. Insurtum serves and the serves of the serves serves of the serves is the serve of the serves of the serves serves condition. Insurtum serves and serve serves of the serves is the serve of the serves of serves of the serves is the serve of the serves of serves of the serves is the serve of the serves of serves of the serves of the serves of the serves at a doctor or pharmackit before use if you are all the serves of the serves of the serves of the serves of the serves of the serves of server serves of the serves of the serves of server serves of the serves of the serves of server serves of the serves of the serves of the model helpor contact a Poison Cortect Center right away. Defension of the serves of the serves of the model before serves wallow it table with a glass of water is the server serves of the serves of the server serves of the serves of the serves of the doctor of the server of the serves of the server serves of the serves of the doctor of the server of the serves of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server server of the server of the server of the server of the server server of the server of the server of the server of the server of the server of the server of the server of	Labeling Format Information Format Description Form Bryle H-boden Noros, Belt, table Drug Facts (continued) 9pt Handar 7pt Body Teat 6pt Bodine 0 5pt Bartne 2 pt Handar 10 pt Ung Tele 10 pt Jatelioation Left Pervision 02
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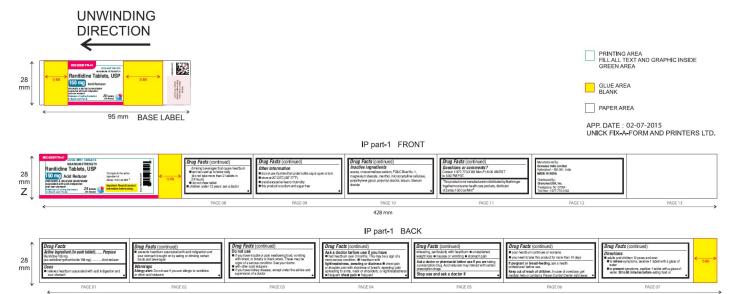
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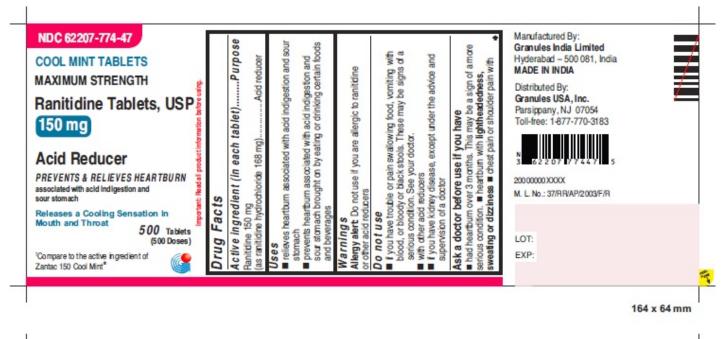
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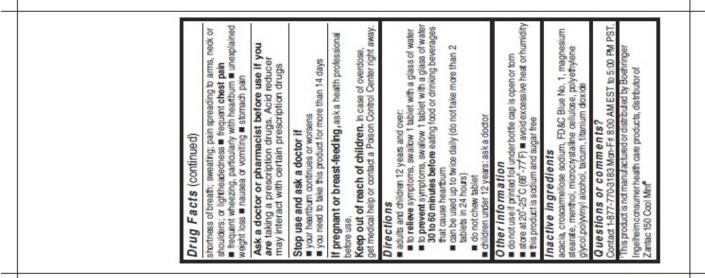
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Format	Description			
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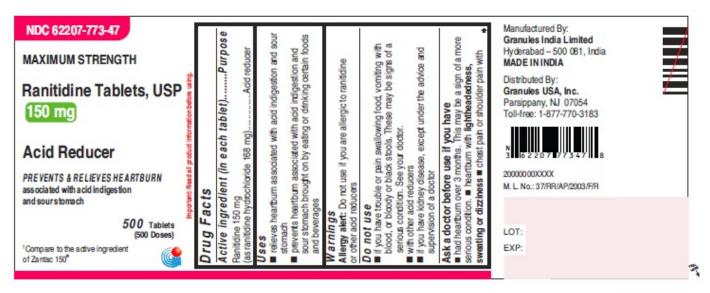
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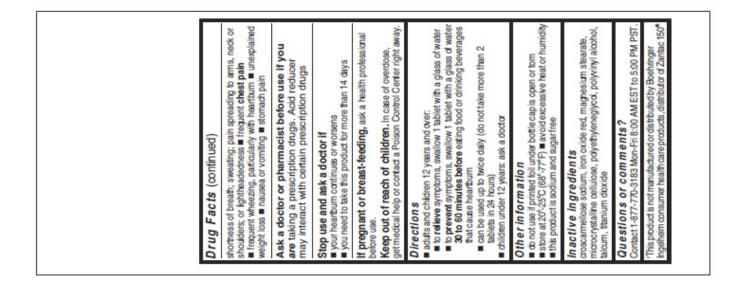




164 x 64 mm



164 x 64 mm



## **RANITIDINE TABLETS, USP 150 mg Cool mint**

No. of Units : 10,000's

Each film coated tablet contains Ranitidine 150 mg (as Ranitidine hydrochloride USP 168 mg)

Batch No. : XXXXXXX

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-774-32

Mfg.Lic.No. : 37/RR/AP/2003/F/R

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.

Country of Origin: INDIA

## **RANITIDINE TABLETS, USP 150 mg**

No. of Units : 10,000's

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**Country of Origin: INDIA** 

# **RANITIDINE TABLETS, USP 150 mg Cool mint**

Each film coated tablet contains Ranitidine 150 mg (as Ranitidine hydrochloride USP 168 mg)

Batch No.	: XXXXXXX	No. of Units	: 5x10,000's
Mfg.Dt.	: MM/YYYY	Gross Wt.	: 00.000 Kg
Exp.Dt.	: MM/YYYY	Tare Wt.	: 00.000 Kg
NDC No.	: 62207-774-36	Net Wt.	: 00.000 Kg
Mfg.Lic.No.	: 37/RR/AP/2003/F/R	Box number	: 000

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.



(01)50362207774364(17)000000(10)XXXXXXX





Product code: 70000001630

# **RANITIDINE TABLETS, USP 150 mg**

Each film coated tablet contains Ranitidine 150 mg (as Ranitidine hydrochloride USP 168 mg)

Batch No.	: XXXXXXX	No. of Units		5x10,000's
Mfg.Dt.	: MM/YYYY	Gross Wt.	:	00.000 Kg
Exp.Dt.	: MM/YYYY	Tare Wt.	:	00.000 Kg
NDC No.	: 62207-773-36	Net Wt.	:	00.000 Kg
Mfg.Lic.No	.: 37/RR/AP/2003/F/R	Box number	:	000

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.



(01)50362207773367(17)000000(10)XXXXXXX



Product code : 70000001629

Ρ	roduct Info	rmation						
P	roduct Type		HUMAN OTC	C DRUG It	em Code (Sour	ce)	NDC:62	207-773
R	oute of Admin	istration	ORAL					
A	ctive Ingred	lient/Acti	ve Moiety					
		I	Ingredient Na	ame			is of ngth	Strengt
	ANITIDINE HYDR NII:884KT10YB7)	ROCHLORID	<b>E</b> (UNII: BK76465	IHM) (RANITIDINE	-	RANITIDINE		150 mg
I r	nactive Ingre	adiants						
	lactive myre	culents	Ingredie	ent Name			c	trength
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			(UNII: M28OL1HH					
	ERRIC OXIDE RE			(10)				
	AGNESIUM STE							
	OLYETHYLENE C							
P(	OLYVINYL ALCO	HOL (UNII: 5	532B59J990)					
T/	ALC (UNII: 7SEV7	J4R1U)						
Τľ	TANIUM DIOXID	<b>E</b> (UNII: 15F	IX9V2JP)					
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<b>*</b> 773-36		00/20/2013	
4 NDC:62207- 773-32	10000 in 1 BAG; Type 0: Not a Co Product	ombination	
	<b>RANITIDINE TA</b>	BLETS, USP 150	) mg
Each film co	pated tablet contains:		•
Ranitidine 1			
	ne hydrochloride USP 168 mg)		
Batch No.		No. of Units : 10,000's	4
Mfg.Dt.	: MM/YYYY		Country of Origin: INDIA
Exp.Dt.	: MM/YYYY		gin:
NDC No.	: 62207-773-32		f Ori
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Storage : St	ore at 20º-25ºC (68º-77ºF) Avoid excessiv	ve heat or humidity	Coun
Caution : Fo	r repacking only.		
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			Product code :
			Prodt
Marketin	g Information		
Marketin Categor		Monograph Marketing S Date	Start Marketing End Date
ANDA	ANDA210243	06/26/2019	

RANITIDINE COOL M ranitidine tablet	IINT				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sour	ce)	NDC:6220	7-774
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ing	redient Name		Basis Strer		Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)			RANITIDINE		150 mg

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

#### **Product Characteristics**

Color	blue	Score	no score
Shape	ROUND	Size	9mm
Flavor	MINT	Imprint Code	150;G
Contains			

### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207- 774-58	2 in 1 CARTON	06/26/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:62207- 774-41	1 in 1 CARTON	06/26/2019	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:62207- 774-47	1 in 1 CARTON	06/26/2019	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:62207- 774-36	5 in 1 CARTON	06/26/2019	
4		10000 in 1 BAG; Type 0: Not a Combination Product		
M	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	IDA	ANDA210243	06/26/2019	

Revised: 1/2023