RANITIDINE- ranitidine tablet RANITIDINE COOL MINT- ranitidine tablet Granules India Ltd				
Ranitidine Tablets				
ACTIVE INGREDIENT(S)				
Ranitidine 150 mg				
PURPOSE				
Acid reducer				
USE(S)				
<ul> <li>relieves heartburn associated with acid indigestion and sour stomach</li> <li>prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages</li> </ul>				
WARNINGS				
<b>Allergy alert:</b> Do not use if you are allergic to ranitidine or other acid reducers				
DO NOT USE				
I 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				
$\ensuremath{\mathbb{I}}$ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness				
□ frequent <b>chest pain</b>				
I frequent wheezing, particularly with heartburn				
□ unexplained weight loss				
🛘 nausea or vomiting				
🛘 stomach pain				

□ kidney disease
<b>Ask a doctor or pharmacist before use if you are</b> taking a prescription drug. Acid reducers may interact with certain prescription drugs.
STOP USE AND ASK DOCTOR IF
<ul><li>your heartburn continues or worsens</li><li>you need to take this product for more than 14 days</li></ul>

# 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 <b>relieve</b> symptoms, swallow 1 tablet with a glass of water
☐ to <b>prevent</b> symptoms, swallow 1 tablet with a glass of water ☐ ☐ <b>30 to 60 minutes before</b> ☐ eating food or drinking beverages that cause heartburn
and 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 0-25 0☐C (68 0☐-77 0☐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 ® 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 Cool Mint\*

**COOL MINT TABLETS** 

# Ranitidine Tablets, USP 150 mg

**Acid Reducer** 

# PREVENTS & RELIEVES HEARTBURN

associated with acid indigestion and sour stomach

20 (2x10) Tablets

Un Varnish area

**Drug Facts** 

Active ingredient (in each tablet)...Purpose Rantidne 150 mg (asrantidne hydrochloride 168 mg)....Acid reducer

■ relieves hearfourn associated with acid indigestion and sour stomach
■ prevents hearfourn associated with acid indigestion and sour stomach

Warnings Allergy alert: Donotuse if you are allergictoranifidine or other acid reduces

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 Ingelhei consumer health care products, distributor of Zantac 150 Cod Mint\*

Inactive ingredents

nocis, cosciemelos sodan, ENC Bas Na. 1, mgrasium
starde, montrol, microsystatine oalubos, pojethylene glycol,
polyvnik dochd, labum, starlum dande.

Read the directions and warnings before use. Keep the carton It contains important information including tips for managing

DO not use

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

■ with other acid reducers

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Manufactured By: Granules India Limited Hyderabad – 500 081, India MADE IN INDIA M. L. No.: 37/RRIAP/2003/F/R

Distributed By: Granules USA, Inc. Parsippany, NJ 07054 Toll-free: 1-877-770-3183

# Drug Facts (continued)

Ask a doctor before use if you have and a had hearbunved months. This rape's a sign of anner serious condition, a hearbun with lightheadedness, swading of diziness a rede paint or studier plan with abstraces of breatt swading, pain spreading to arms, next or shoulders; or phin hearbunves are hequer feets plan is received the plan plan and provided by the plan and plan a

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

f pregnant or breast-feeding, ask a health professional ■ yourhearthum continues orworsens ■ younsed to take this product formore than 14 days

Keep out of reach of children, in case of overtose, work at hale or contact a Poison Control Center right and

Experient symptoms, evaline 1 tablet with a glass of water 30 b GM milleds before sating boot ordinating bearingss. That cause hearthur before sating boot ordinating bearingss.

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 Example sedup to knicedally (do not take more than a chockew ballet.)

if you smake, guit smoking · Raise the head of your bed . Wearloose fitting clothing around your stomach



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# Tips formanaging 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, fatly and fried foods, choodate, caffeine, alcohol, even some fruits and vegetables. Eat slowly and do not eatbig meals
- · if you are overweight, lose weight



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NDC 62207-774-47

**COOL MINT TABLETS** 

MAXIMUM STRENGTH

Ranitidine Tablets, USP 150 mg

**Acid Reducer** 

PREVENTS & RELIEVES HEARTBURN

associated with acid indigestion and sour stomach

Releases a Cooling Sensation in Mouth and Throat

500 Tablets (500 Doses)

\*Compare to the active ingredient of Zantac 150 Cool Mint®



# Drug Facts

Active ingredient (in each tablet).......Purpose antidne 150 mg as santidne hydrochloride 168 mg)........Acid seducer

stomach prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings
Allergy slert: Do not use if you are allergic to ranifidine or other acid reducers

## Do not use

if you have trouble or pain swellowing 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 you have

Ask a doctor before use if you have "had hearburn over 3 mornhs. This may be a sign of a more serious condition. \* hearburn with lighthead-diness, sweating or disziness \* obest pain or shoulder pain with shortness of beach; sweating pain speading to arms, next or shoulders; or lighthead-diness \* fequent cheet pain \* frequent wheezing, particularly with hearburn unrespland registloss \* rauses or vomiting \* stomach pain \* kidney disease.

## Drug Facts (continued)

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

If pregnant or breast-feeding, ask a health professional

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

- Directions

  adds and children 12 years and over.

  a of the symptoms, swallow 1 table with a glass of water

  to prevent amptoms, swallow 1 tablet with a glass of water

  to prevent amptoms, swallow 1 tablet with a glass of water

  30 to 60 minutes before eating food or drinking beverages

  that cause heartbun

  a can be used up to twice daily (do not take more than 2
  sables in 24 hours)
- children under 12 veats; ask a doctor

Other information

#do not use if printed foil under bottle cap is open or ton

#stors #25".25"C (66".77"F) # avaid excessive heat or humidity

#this product is sodium and sugarfiee

Inactive ingredients
acada, coscarmellose sodium, FDSC Blue No. 1, magnesium
steasate, merhot, microsystalline cellubse, polyethylene glycol,
polyvinyl alcohol, talbum, ttanium dioxide

Questions or comments? Contact 1-877-770-3183 Mon-Fri8:00 AM EST to 5:00 PM EST.

<sup>5</sup>This product is not manufactured or distributed by Boehringer lingelheim consumer he alth care products, distributor of Zantac 150 Cool Mint<sup>6</sup>

- Do not eat late at night, or just before bedtime
- . Certain foods or difriks are more likely to gause heartburn, such as rich, spicy, faitly and fried foods, chocolate, attierie, alcohol, even some fruits and vegetables.
  Eatslowly and do not eat bigmeals
- · if you are overweight, lose weight

- If you smoke, guit smoking
   Raisethe head of your bed
   Wear loose fitting dothing around your stormach

Read the directions and warnings before use. Keep the carton . It contains import an information including tips for managing heartburn.

Manufactured By: Granufes India Limited Hyderabad – 500 081, India MADE IN INDIA

37/RR/AP/2003/F/R

Distributed By: Granules USA, Inc. Parsippony, NJ 07054 Tol-free: 1-877-770-3183

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Manufactured By: Granules India Limited Hyderabad – 500 081, India

Read the directions and warmings before use. Keep the carbon it contains important information including tips for managing

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# NDC 62207-774-41

# **COOL MINT TABLETS**

MAXIMUM STRENGTH

# Ranitidine Tablets, USP

# 150 mg

# **Acid Reducer**

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Releases a Cooling Sensation in Mouth and Throat

<sup>1</sup>Compare to the active ingredient of Zantac 150 Cool Mint <sup>e</sup>

24 Tablets (24 Doses)



# Drug Facts

Active ingredient (in each tablet) Purpose

Ranitidine 150 mg

(as ranitidine hydrochloride 168 mg). Acid reducer

wes heartburn associated with acid indigestion

 releves nearborn associated with acid indigesion and sour stomach
 prevents hearborn associated with acid indigesion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings
Allergy abort: 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 you have
had heartburn over 3 months. This may be a sign of a more serious condition.

sign of a more seniors containon.

The hearburn with lightheadedness, sweating or dizariness at chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, nock or shoulders; or lightheadedness are frequent cheest pain at frequent these ring, particularly with hearburn a unexplained weight

# Drug Facts (continued)

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 a doctor if

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

If pregnant or breast-feeding, ask a health

Keen 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:
   b relieve symptoms, swallow 1 tablet with a glass of wate
- glass of wate 
  to prevent symptoms, swallow 1 tablet with a 
  glass of water 30 to 60 minutes before eating 
  food or drinking beverages that cause hearthur 
  to an be used up to twice daily (do not take more 
  than 2 tablets in 24 hours)
- do not chew tablet
   children under 12 years: ask a doctor

# Other information

# Drug Facts (continued)

torn ■store at 20°-25°C (68°-77°F) ■ avoid excessive heat or humidity = this product is sodium and sugar fre

Labeling Format Information

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Format

Drug Facts

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Drug Facts (or

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# Inactive ingredients

acacia, croscarmellose sodium, FD&C Blue No. 1, magnesium stearate, menthol, microcrystalline celfulose, 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 consumer health care products, distributor of Zantac 150 Cool Mint

## 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 and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.
- Eatslowly and do not eat big meals
- if you are overweight, lose weight
- if you smoke, quitsmoking
- Raise the head of your bed
- Wearloose fitting dothing around your stomach

NDC 62207-773-58

<sup>†</sup>Compare to the active ingredient of Zantac 150<sup>e</sup>

MAXIMUM STRENGTH

# Ranitidine Tablets, USP 150 mg

**Acid Reducer** 

# PREVENTS & RELIEVES HEARTBURN

associated with acid indigestion

20 (2x10) Tablets



Read the directions and warmings before use. Keep the carlor It contains important information including tips for managing heartburn.

Drug Facts

Uses

relieves heartburn associated with acid indigestion and sour stomach
prevents heartburn associated with acid indigestion and sour stomach

Warnings
Allergy alert: Do not use if you are allergic to ranifidine or other acid red

Do not use

blor for case

"If you have thouble or pain swallowing food, vomiting with blood, or bloody o
blacks bods. These may be signs of a serious condition. See your doctor.

■ with other acid reducers

rought on by eating or drinking certain foods and beverage

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Manufactured By: Granules India Limited Hyderabad – 500 081, India MADE IN INDIA

# Drug Facts (continued)

# Ask a doctor before use if you have

Tips for managing heartburn

some fruits and vegetables.

• Eat slowly and do not eat big meals if you are overweight, lose weight

. Do not lie flat orbend oversoon after eating

Do not eat late at night, or just before bedtime

# ■ had heartburn over 3 months. This maybe a sign of amore serious condition. ■ manufactur with light headdheass, seventing or dischess with self pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or fight headdheass. ■ Request thest pain is required the particularly with heartburn pain is required the particularly with heartburn particularly with heartburn and particularly with heartburn and particularly with heartburn pain.

Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, even

# Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reduces may in certain prescription drugs. Stop use and ask a doctor if

# Keep out of reach of children, in case of overdo germedical help or contact a Poison Control Center right away yourheartbun confinues or worsens youneed to take this product formore than 14 days preginant or breast-feeding, ask ahealth

# e symptoms, swallow 1 tablet with a glass of water nt symptoms, swallow 1 tablet with a glass of water minutes before eating tood or drinking beverages

# thum to twice daily (do not take more than

if you smake, quit smaking

5:00 PM EST

This productisnot manufacture dor distributed by Boeh finger Ingelheim consumer health care products, distributor of Zantac 150\*

 Raise the head of your bed Wearloose fitting clothing around your stomach









Labeling Format Information		
Format	Description	
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# NDC 62207-773-47

MAXIMUM STRENGTH

# Ranitidine Tablets, USP 150 mg

# **Acid Reducer**

PREVENTS & RELIEVES HEARTBURN

associated with acid indigestion and sour stomach

> 500 Tablets (500 Doses)

<sup>1</sup>Compare to the active ingredient of Zantac 150<sup>6</sup>



# Drug Facts

Active ingredient (in each tablet)......Purpose Raritidne 150 mg (as raritidne hydrochioide 168 mg)........Add mducer

- relieves heartburn associated with add indigestion and so
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking cestain food and beverages

Warnings
Allergy alert: Do not use if you are allergic to sanitidine 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.

#If other acid reducers

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Alak a doctor before use if you have
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## Drug Facts (continued)

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 hearthum continues or worsens

  you need to take this product for more than 14 days.

# If pregnant or breast-feeding, ask a health professional

Keep out of reach of children, in case of overdose et medical help or contact a Poison Control Center right away

- Directions

  adds and children 12 years and over:

  a brelieve symptoms, swallow I tablest with a glass of water

  b prelieve symptoms, swallow I tablest with a glass of water

  b prevent symptoms, swallow I tables with a glass of water

  30 to 60 minutes before eating tood or of sinking beverages

  that cause hearthurn

  can be used up to twice daily (do not take more than 2 tables in 34 hours)

  whicher under 12 years, ask a dooter

  When (if the content of t

Other information

-do not use if printed foil under bottle cap is open or tom

-store at 22\*-25\*\*C(68\*-77\*\*) • avoid excessive heat or humidity

-this product is sodium and sugar free

Inactive ingredients croscamelose sodium, iron oxide red, magnesium stearate, microcrystaline cellulose, polyethyleneglycol, polyvinyl alcohol, talcum, ttanium 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 consumer health care-products, distributor of Zantac 150"

- Tips for managing heartburn

  Do not lie fist or bendover soon after resting

  Do not eat lise at night, or just before bedtime

  Certain foods not finis armore likely to cause
  heartburn, such as rich, sploy, faity and field foods, chocolate, caffeine, alcohol, even somefruits and vegetables. Eatslowly and do not eat big meals

- If you are overweight, lose weight
  If you smoke, gut smoking
- Baisetheheadofvourbed
- Wear loose fitting clothing around your stomach

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Distributed By: Granules USA, Inc. Parsippany, NJ 07054 Toll-free: 1-877-770-3183

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# NDC 62207-773-41

## MAXIMUM STRENGTH

# Ranitidine Tablets, USP

150 mg

# **Acid Reducer**

PREVENTS & RELIEVES HEARTBURN

associated with acid indigestion and sour stomach

<sup>1</sup>Compare to the active ingredient of Zantac 150<sup>a</sup>

24 Tablets (24 Doses)



# Drug Facts

Active ingredient (in each tablet) .Purpose

Ranitidine 150 mg as ranitidine hydrochloride 168 mg). Acid reducer

- relieves heartburn associated with acid indigestion and sour stomach
- and sour stomach prevents hearburn 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 slools. These may be signs of a serious condition. See your doctor. with other acid reducers

Ask a doctor before use if you have

In had hearburn over 3 months. This may be a sign
of a more serious condition. In hearburn with
lightheadedness, sweating or dizziness

In the pain or shoulder pain with shortness of
breath; sweating; pain spreading to arms, neck or
shoulders; or lighthe adedness In frequent

chest pain = frequent wheezing, particularly with

# Drug Facts (continued)

- 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 a doctor if

- you need to take this product for more than
- 14 days

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.

## Directions

- 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.)

  children under 12 years ask a doctor

# Other information

# Drug Facts (continued)

orn store at 20°-25°C (68°-77°F) avoid excessive eat or humidity this product is sodium and sugar for

# Inactive ingredients

croscarmellose sodium, iron oxide red, magnesium stearate, microdystalline cellulose, polyethyleneglyco polyvinyli 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 Inge heim consumer health care products, distributor of Zantac 150°

# 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
- hear burn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.
- Eat slowly and do not eat big me als
- if you are overweight, bse weight
- if you smoke, quitsmoking
- Raise the head of your bed
- Wea rloose fitting dothing around your stomach









PAPER AREA

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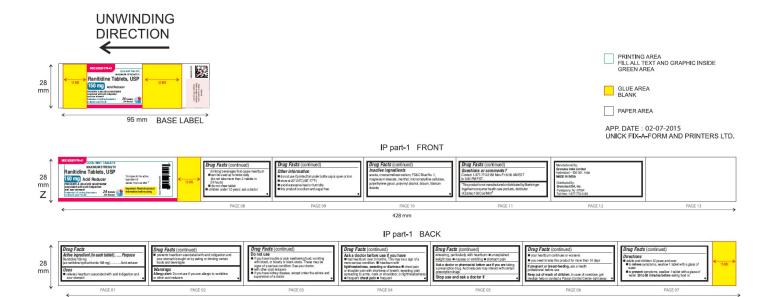
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# NDC 62207-774-47

# COOL MINT TABLETS

MAXIMUM STRENGTH

# Ranitidine Tablets, USP 150 mg

# Acid Reducer

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Releases a Cooling Sensation in Mouth and Throat

500 Tablets (500 Doses)

\*Compare to the active ingredient of Zantac 150 Cool Mint\*

Drug Facts

Active ingredient (in each tablet)......Purpose

relieves heartburn associated with acid indigestion and sour

Acid reducer

as ranitidine hydrochloride 168 mg)

Panitidine 150 mg

sour stomach brought on by eating or drinking certain foods prevents heartburn associated with acid indigestion and stomach

# Allergy alert. Do not use if you are allergic to ranitione or other acid reducers Warnings

 I you have trouble or pain swallowing food, vorniting with blood, or bloody or back stools. These may be signs of a serious condition. See your doctor. Do not use

 f you have kidney disease, except under the advice and with other acid reducers supervision of a doctor

Ask a doctor before use if you have

had heartburn over 3 months. This may be a sign of a more serious condition. 

The heartburn with lightheadedness, sweating or dizziness = chest pain or shoulder pain with Manufactured By: Granules India Limited Hyderabad - 500 081, India MADE IN INDIA

Distributed By: Granules USA, Inc. Parsippany, NJ 07054 Toll-free: 1-877-770-3183



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164 x 64 mm

# Drug Facts (continued)

shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness **=** frequent **chest pain** 

 frequent wheezing, particularly with heartburn unexplained weight loss unausea or vomiting ustomach pain Ask a doctor or pharmacist before use if you

are taking a prescription drugs. Acid reducer may interact with certain prescription drugs

 your heartburn confinues or worsens
 you need to take this product for more than 14 days Stop use and ask a doctor if

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away pregnant or breast-feeding, ask a health professional perfore use.

Directions

 to relieve symptoms, swallow 1 tablet with a glass of water adults and children 12 years and over:

 to prevent symptoms, swallow 1 tablet with a glass of water
 30 to 60 minutes before eating food or drinking beverages can be used up to twice daily (do nottake more than 2 tablets in 24 hours) that cause heartburn

children under 12 years: ask a doctor do not chew tablet

Other information

store at 20°-25°C (68°-77°F) a avoid excessive heat orhumidity donot use if printed foll underbottle cap is open or torn

icacia, croscarmellose sodium, FD&C Blue No. 1, magnesium this product is sodium and sugar free nactive ingredients

stearate, menthol, microcrystaline cellulose, polyethylene

glycol,polyvinyl alcohol, talcum, titanium doxide

Questions or comments?

ntact 1-877-770-3183 Mon-Fit 8:00 AM EST to 5:00 PM PST product is not manufactured or distributed by Boehringer ngelheim consumerhealth care products, distributor of

164 x 64 mm

antac 150 Cool Minif

# NDC 62207-773-47

# MAXIMUM STRENGTH

# Ranitidine Tablets, USP

# 150 mg

# **Acid Reducer**

PREVENTS & RELIEVES HEARTBURN associated with a cid indigestion and sour stomach

> 500 Tablets (500 Doses)

Compare to the active ingredient of Zantac 150



# Drug Facts

Active ingredient (in each tablet)......Purpose

# E 168 as ranitidine hydrochloride Ranitdine 150 mg

reducer

Acid

relieves heartburn associated with acid indigestion and sour prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods stomach ses

# and beverages Narnings

# Allergy alert: Do not use if you are allergic to ranitdine

# 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

If you have kidney disease, except under the advice

Ask a doctor before use if you have supervision of a doctor

had heartburn over 3 months. This may be a sign of a more serious condition. In heartburn with lightheadedness, sweating or dizziness - chest pain or shoulder pain with

Distributed By: Granules USA, Inc. Parsippany, NJ 07054 Toll-free: 1-877-770-3183 200000000XXXX M. L. No.: 37/RR/AP/2003/F/R

LOT:

EXP:

Manufactured By:

MADE IN INDIA

Granules India Limited

Hyderabad - 500 081, India



164 x 64 mm

3

# Drug Facts (continued)

shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness = frequent chest pain frequent wheezing, particularly with heartburn 

unexplained

Ask a doctor or pharmacist before use if you are taking a prescription drugs. Acid reducer may interact with certain prescription drugs

weight loss ■ nausea or vomiting ■ stomach pain

Stop use and ask a doctor if

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

pregnant or breast-feeding, ask a health professional

get medical help or contact a Poison Control Center right away Keep out of reach of children. In case of overdose

Directions

adults and children 12 years and over:

 to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages to relieve symptoms, swallow 1 tablet with a glass of water

 can be used up to twice daily (do not take more than 2 children under 12 years: ask a doctor hat cause heartburn tablets in 24 hours)

Other information

■ do not use if printed foil under bottle cap is open or torn ■ store at 20°-25°C (68°-77°F) ■ avoid excessive heat or humidity

microcnystaline cellulose, polyethyleneglycol, polyvinyl alcohol croscamellose sodium, iron oxide red, magnesium stearate this product is sodium and sugarfree Inactive ingredients

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST Questions or comments?

alcum, tranium doxide

This product is not manufactured or distributed by Boehringer ingelheim consumer health care products, distributor of Zantac 150°

# **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 : 10,000's

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

Product code: 700000001630

# **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 : 10,000's

Mfg.Dt. : MM/YYYY
Exp.Dt. : MM/YYYY

NDC No. : 62207-773-32

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

Product code: 700000001629

# **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 Gross Wt. Mfa.Dt. : MM/YYYY : 00.000 Kg Tare Wt. : 00.000 Kg Exp.Dt. : MM/YYYY 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: 700000001630

# **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

# **RANITIDINE**

ranitidine tablet

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-773			
Route of Administration	ORAL					

	Active Ingredient/Active Moiety					
ı	Ingredient Name	Basis of Strength	Strength			
l	RANITIDINE HYDRO CHLO RIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7)	RANITIDINE	150 mg			

Inactive Ingredients				
Ingredient Name	Strength			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics					
Color	brown	Score	no score		
Shape	ROUND	Size	9mm		
Flavor		Imprint Code	150;G		
Contains					

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:62207-773-58	2 in 1 CARTON	06/26/2019			
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:62207-773-41	1 in 1 CARTON	06/26/2019			
2		24 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:62207-773-47	1 in 1 CARTON	06/26/2019			
3		500 in 1 BOTTLE; Type 0: Not a Combination Product				
4	NDC:62207-773-36	5 in 1 CARTON	06/26/2019			
4	NDC:62207-773-32	10000 in 1 BAG; Type 0: Not a Combination Product				

# **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 : 10,000's

Mfg.Dt. : MM/YYYY Exp.Dt. : MM/YYYY

NDC No. : 62207-773-32

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

Product code: 70000001629

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210243	06/26/2019	

# **RANITIDINE COOL MINT**

ranitidine tablet

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v	MO	411	ct	m	OP	cm	tion
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-774
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Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDRO CHLO RIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7)	RANITIDINE	150 mg

Inactive Ingredients				
Ingredient Name	Strength			
ACACIA (UNII: 5C5403N26O)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
CDOSCADMELLOSE SODIUM (LINII) MOSOLI LILLIAS)				

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
MAGNESIUM STEARATE (UNII: 70097M6130)		
MENTHOL (UNII: L7T10 EIP3A)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL (UNII: 532B59J990)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

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

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
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				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210243	06/26/2019		

# Labeler - Granules India Ltd (915000087)

# Registrant - Granules India Ltd (918609236)

Establishment					
Name	Address	ID/FEI	Business Operations		
Granules India Ltd		918609236	manufacture(62207-773, 62207-774)		

Revised: 11/2019 Granules India Ltd