

RUGBY CALCIUM CARBONATE 10 GR- antacid tablets tablet, chewable
Aphena Pharma Solutions - Tennessee, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Calcium carbonate 10 gr (648 mg)

Purpose

Antacid

Uses

Relieves:

- acid indigestion
- heartburn
- sour stomach
- acid indigestion
- upset stomach associated with these symptoms

Warnings

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

Stop use and ask a doctor if symptoms last more than 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Directions

- take one to four tablets daily
- do not take more than 4 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks

Other Information

each tablet contains: calcium 260mg

store at room temperature 15⁰-30⁰C (59⁰-86⁰F)

Inactive ingredients

corn starch, crospovidone, magnesium stearate, maltodextrin

Questions or comments

1-800-645-2158

Repackaging Information

This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

| Count | 648mg |
|--------------|--------------|
| 30 | 43353-958-30 |
| 60 | 43353-958-53 |
| 90 | 43353-958-60 |
| 100 | 43353-958-65 |
| 180 | 43353-958-80 |
| 200 | 43353-958-85 |
| 270 | 43353-958-92 |

Store between 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20160606DH

PRINCIPAL DISPLAY PANEL - 648mg

NDC 43353-958 - **Calcium Carbonate** 648mg - Rx Only

Calcium Carbonate

648mg 30 Tablets



N 43353-0958-30

Calcium Carbonate

648mg 30 Tablets

NDC # 43353-0958-30

Store between 20-25 degrees C (68-77 degrees F).
See USP Controlled Room Temperature.
Dispense in a tight light-resistant container as defined by USP.
Keep this and all drugs out of the reach of children.

Mfg. By: Raritan Pharmaceuticals
East Brunswick, NJ

Repackaged by Aphena Pharma
Cookeville, TN 38506

Calcium Carbonate 648mg 30 Tablets

Batch:
Exp:
Lot:



N 43353-0958-30

RUGBY CALCIUM CARBONATE 10 GR

antacid tablets tablet, chewable

Product Information

| | | | |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43353-958(NDC:0536-1024) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|-------------------|--------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB) | CALCIUM CARBONATE | 648 mg |
|---|-------------------|--------|

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | RP106 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:43353-958-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/02/2014 | |
| 2 | NDC:43353-958-53 | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2014 | |
| 3 | NDC:43353-958-60 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2014 | |
| 4 | NDC:43353-958-65 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/26/2014 | |
| 5 | NDC:43353-958-80 | 180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2014 | |
| 6 | NDC:43353-958-85 | 200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/29/2014 | |
| 7 | NDC:43353-958-92 | 270 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331 | 02/07/2014 | |

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|---------------------|
| Aphena Pharma Solutions - Tennessee, LLC | | 128385585 | REPACK(43353-958) |