

CALCIUM ANTACIDEXTRA STRENGTH EXTRA STRENGTH- calcium carbonate tablet, chewable

Rugby Laboratories

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.

Rugby. Calcium Antacid Tablets Drug Facts

Active ingredient (per tablet)

Calcium Carbonate USP 750mg

Purpose

Antacid

Uses

relieves

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

Warnings

Ask a doctor or pharmacist before use if you are

- presently taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

- do not take more than 10 tablets in 24 hours
- if pregnant do not take more than 6 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor

Keep out of reach of children.

Directions

- **adults and children 12 years of age and over:** chew 2 - 4 tablets as symptoms occur, or as directed by a doctor
- do not take for symptoms that persist for more than 2 weeks unless advised by a doctor

Other information

- each tablet contains: elemental calcium 300 mg
- Store at room temperature. Keep the container tightly closed.

Inactive ingredients

adipic acid, D&C red #27 lake, D&C yellow #10 lake, dextrose, FD&C blue #1 lake, FD&C yellow #6 lake, flavors, magnesium stearate, maltodextrin, starch, sucralose

Questions or comments ?

1-800-645-2158

Principal Display Panel

SAFETY SEALED. DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING.

COMPARE TO the active ingredient of TUMS® EXTRA STRENGTH

NDC 0536-1049-22

Rugby®

CALCIUM

Antacid

Tablets

Extra Strength

Calcium Carbonate 750 mg

ASSORTED FRUIT

Naturally & Artificially Flavored

96 Chewable TABLETS

GLUTEN-FREE

*This product is not manufactured or distributed by GlaxoSmithKline LLC,

Owner of the registered trademark,

Extra Strength Tums®

Distributed by Rugby laboratories

17177 n Laurel Park Drive, Suite 233

Livonia, MI, 48152, USA

www.rugbylaboratories.com



Drug Facts

| Active ingredient (per tablet) | Purpose |
|----------------------------------|---------|
| Calcium Carbonate USP 750mg..... | Antacid |

Uses relieves • heartburn
• acid indigestion • sour stomach
• upset stomach associated with these symptoms

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

When using this product

- do not take more than 10 tablets in 24 hours
- if pregnant do not take more than 6 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor

Keep out of reach of children.

Directions

- adults and children 12 years of age and over: chew 2-4 tablets as symptoms occur, or as directed by a doctor
- do not take for symptoms that persist for more than 2 weeks unless advised by a doctor

Other information

- each tablet contains: elemental calcium 300mg
- store at room temperature. Keep the container tightly closed.

Inactive ingredients adipic acid, D&C red #27 lake, D&C yellow #10 lake, dextrose, FD&C blue #1 lake, FD&C yellow #6 lake, flavors, magnesium stearate, maltodextrin, starch, sucralose.

Questions or comments? 1-800-645-2158

Safety sealed: Do not use if printed seal under cap is torn or missing

GLUTEN-FREE

*This product is not manufactured or distributed by GlaxoSmithKline LLC, owner of the registered trademark, Extra Strength Tums®.

Distributed by Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152, USA
www.rugbylaboratories.com

P-107 REV. 05/17 Re-Order No. 370389

LOT:
EXP:
102AF96RGLB

3 05361 04922 5

CALCIUM ANTACIDEXTRA STRENGTH EXTRA STRENGTH

calcium carbonate tablet, chewable

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1049 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------|-------------------|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D) | CALCIUM CARBONATE | 750 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
| | |

| | |
|------------------------------------------------------|--|
| ADIPIIC ACID (UNII: 76A0JE0FKJ) | |
| D&C RED NO. 27 (UNII: 2LRS185U6K) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|-----------------|-------------------------------------|---------------------|----------|
| Color | YELLOW, GREEN, RED, ORANGE | Score | no score |
| Shape | ROUND | Size | 17mm |
| Flavor | FRUIT (lemon, orange, cherry, lime) | Imprint Code | RP102 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0536-1049-22 | 96 in 1 BOTTLE; Type 0: Not a Combination Product | 03/15/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part331 | 03/15/2015 | |

Labeler - Rugby Laboratories (079246066)