

**ALKA-SELTZER HEARTBURN RELIEFCHEWS- calcium carbonate tablet, chewable**  
**Bayer HealthCare 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.*

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**Alka-Seltzer® Heartburn ReliefChews™**

***Drug Facts***

**Active ingredient (in each chewable tablet)**

Calcium carbonate 750 mg

**Purpose**

Antacid

**Uses**

for the relief of:

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

**Warnings**

**Do not use if** you have ever had an allergic reaction to this product or any of its ingredients

**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 chewable tablets in a 24-hour period
- do not use the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician
- constipation may occur

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

**Keep out of reach of children.**

**Directions**

- adults and children 12 years and over: chew and swallow 1-2 chewable tablets every 2 to 4 hours as symptoms occur, or as directed by a doctor
- children under 12 years: consult a doctor
- do not take more than 10 chewable tablets in a 24-hour period

**Other information**

- **each chewable tablet contains:** calcium 300 mg
- contains FD&C Yellow No. 5 (tartrazine) as a color additive

- store at room temperature. Avoid humidity. Close cap tightly after use.

### **Inactive ingredients**

acacia, beeswax, carmine, carnauba wax, citric acid, corn starch, corn syrup, DL-alpha tocopherol, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #5 lake (tartrazine), FD&C yellow #6, FD&C yellow #6 aluminum lake, FD&C yellow #6 lake, flavors, hydrogenated coconut oil, medium chain triglycerides, methyl paraben, modified starch, phosphoric acid, pregelatinized modified starch, propyl paraben, propylene glycol, purified water, shellac, sodium benzoate, sorbic acid, sorbitol, soy lecithin, sucrose, titanium dioxide

### **Questions?**

**1-800-986-0369** (Mon – Fri 9AM – 5PM EST) or [www.alkaseltzer.com](http://www.alkaseltzer.com)

Dist. by:  
Bayer HealthCare LLC  
Whippany, NJ 07981

### **PRINCIPAL DISPLAY PANEL - 36 Tablet Bottle Label**

assorted fruit

***Alka-***

***Seltzer***®

*Calcium Carbonate /*

*Antacid*

**EXTRA STRENGTH**

***HEARTBURN***

***RELIEFCHEWS***™

**Fast Powerful Relief**

**36 CHEWABLE TABLETS**



Do not use if safety seal bearing "SEALED for YOUR PROTECTION" under cap is torn or missing

Bayer, the Bayer Cross, Alka-Seltzer and ReliefChews are registered trademarks of Bayer.

Made in the USA of US & Imported Materials  
Dist. by: Bayer HealthCare LLC  
Whippany, NJ 07981

**Bayer**

C5108

<p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>● adults and children 12 years and over: fully chew then swallow 1 or 2 chewable tablets as symptoms occur or as directed by a doctor</li> <li>● children under 12 years: consult a doctor</li> <li>● do not take more than 5 chewable tablets in a 24-hour period</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>● each chewable tablet contains calcium 300 mg</li> <li>● contains FD&amp;C yellow No. 5 (tartrazine) as a color additive</li> <li>● store at room temperature. Avoid humidity.</li> <li>● close cap tightly after use.</li> </ul> <p><b>Inactive ingredients</b> saccharin, carmine, carnauba wax, citric acid, corn starch, corn syrup, DL-alpha tocopherol, FD&amp;C blue #1 aluminum lake, FD&amp;C red #40 aluminum lake, FD&amp;C yellow #5 lake (tartrazine), FD&amp;C yellow #6, FD&amp;C yellow #6 aluminum lake, FD&amp;C yellow #5 lake, flavors, hydrogenated coconut oil, hydrogenated vegetable oil, lecithin, medium chain triglycerides, methyl paraben, modified starch, phosphoric acid, pregelatinized modified starch, polyd paraben, propylene glycol, shaker, sodium benzoate, sorbic acid, sorbitol, sugar, titanium dioxide, water, white wax</p> <p><b>Questions or comments?</b> 1-800-996-0369</p>	
<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each chewable tablet)</b> Calcium carbonate 750 mg Antacid</p> <p><b>Uses for the relief of:</b></p> <ul style="list-style-type: none"> <li>● acid indigestion</li> <li>● heartburn</li> <li>● sour stomach</li> <li>● upset stomach associated with these symptoms</li> </ul> <p><b>Warnings</b></p> <p>Do not use if you have ever had an allergic reaction to this product or any of its ingredients</p> <p>Ask a doctor or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>● do not take more than 5 chewable tablets in a 24-hour period</li> <li>● do not use the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician</li> <li>● constipation may occur</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p>	<p><b>Purpose</b> Antacid</p>



## ALKA-SELTZER HEARTBURN RELIEFCHEWS

calcium carbonate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0221
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	750 mg	

Inactive Ingredients	
Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
ACACIA (UNII: 5C5403N26O)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CORN SYRUP (UNII: 9G5L16BK6N)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROGENATED COCONUT OIL (UNII: JY810XM1OM)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

<b>METHYL PARABEN</b> (UNII: A2I8C7H9T)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	yellow, orange, pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	18mm
<b>Flavor</b>	LEMON, ORANGE, STRAWBERRY	<b>Imprint Code</b>	AS
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0221-36	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2014	
2	NDC:0280-0221-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2014	
3	NDC:0280-0221-12	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2014	
4	NDC:0280-0221-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/12/2015	
5	NDC:0280-0221-08	8 in 1 POUCH; Type 0: Not a Combination Product	03/23/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/15/2014	

**Labeler** - Bayer HealthCare LLC. (112117283)