

**GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled  
SuperValu (Equaline)**

*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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**DRUG FACTS**

**Active Ingredient (in each softgel)**

Simethicone 125 mg

**Purpose**

Antiflatulent (Antigas)

**Use**

- relieves bloating, pressure, or fullness commonly referred to as gas.

**Warnings**

**Stop use and ask a doctor if**

condition persists

**If pregnant or breast- feeding,**

ask a health care 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:** swallow with water 1 or 2 softgels as needed after meals and at bedtime.
- do not exceed 4 softgels in 24 hours except under the advice and supervision of a physician

**Other information**

- store at controlled room temperature 15°-30°C (59°-86°F)
- protect from heat and moisture
- \*This product is not manufactured or distributed by Novartis Consumer Health Inc., owner of the registered trademark Extra Strength Gas- X®

**Inactive Ingredients**

D&C Yellow #10, edible ink, FD&C Blue #1, FD&C Red #40, gelatin, glycerin, peppermint oil, purified water, sorbitol special, and titanium dioxide.

**Questions or comments?**

call 1-877-932-7948

**Principal Display Panel**

Compare to Extra Strength Gas-X® active ingredient\*

Extra Strength

**Gas Relief**

Simethicone 125 mg

relief of:

bloating, pressure, fullness and gas

**EACH DOSE IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**DISTRIBUTED BY:**

**SUPERVALU INC.**

**EDEN PRAIRIE, MN 55344 USA**

**PRODUCT OF USA**

**Product Label**



Simethicone 125 mg

## GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-550
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	PO
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-550-50	5 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:41163-550-30	2 in 1 CARTON		
2		15 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	07/08/2010	

**Labeler** - SuperValu (Equaline) (006961411)

Revised: 10/2012

SuperValu (Equaline)