

PLEO ALKALA ANTACID- sodium bicarbonate, potassium bicarbonate and sodium citrate powder

Sanum Kehlbeck GmbH & Co. KG

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.

"The Original"

Pleo™ Alkala

Antacid

Powder

5.3 oz

(150 g)

Drug Facts

<i>Active Ingredients</i>	<i>Purposes</i>
Potassium bicarbonate (7.8%)	Antacid
Sodium bicarbonate (78%)	Antacid
Sodium citrate (1.6%)	Antacid

Uses

Relieves:

- Heartburn
- Sour stomach
- Acid indigestion
- Upset stomach associated with these symptoms

Warnings

Ask a doctor or pharmacist before use

- if you have kidney disease or are on a sodium-restricted diet.
- if you are taking a prescription drug. Antacids may interact with certain prescription drugs.
- if you are pregnant or nursing a baby.

Stop use and ask a doctor

- if symptoms or maximum dosage lasts more than 2 weeks.
- may have laxative effect or cause constipation in some users.

Keep out of reach of children.

Tamper Evident

This container has been designed for your safety to ensure product freshness. Do not use after expiration date. Do not use if the seal between the cap and container is broken or missing or imprinted security strip on carton is torn.

Directions

- Use enclosed spoon. Take one spoonful in the morning with a glass of water. If needed, take a second spoonful in the evening, or as directed by a doctor.
- Do not take more than 2 spoonfuls in a 24-hour period. If you are over 60 years old, do not take more than 1 spoonful. Not for children under 12 years.
- Do not take maximum dose for more than 2 weeks.

Other information

- Do not use after expiration date.
- Store at room temperature. Protect from heat and light.
- Sodium per spoonful 1500 mg.
- Potassium per spoonful 190 mg.

Inactive ingredients

calcium lactate, sea salt, silica, sodium sulfate

Rev. 03/2007

Made in Germany by
Sanum-Kehlbeck GmbH
Germany

Distributed by:
SANUM USA Corp.
1465 Slater Road, Ferndale, WA 98248

PRINCIPAL DISPLAY PANEL - 150 g Carton

"The Original"

Pleo™ Alkala

**Antacid
Powder**

**5.3 oz
(150 g)**

6001-1

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Lot No.

Expiration Date

Made in Germany by
Sturm-Kohlbeck GmbH
Germany

Distributed by:
Santitas USA Corp.
1865 Slater Road, Fort Worth, TX 76116

Drug Facts (continued)**Directions**

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Rev. 03/2007

6001-1

PLEO ALKALA ANTACID

sodium bicarbonate, potassium bicarbonate and sodium citrate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60681-6001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium bicarbonate (UNII: 8MDF5V39QO) (sodium cation - UNII:LYR4M0NH37)	sodium bicarbonate	11.70 g in 150 g
potassium bicarbonate (UNII: HM5Z15LEBN) (potassium cation - UNII:295O53K152)	potassium bicarbonate	117 g in 150 g
sodium citrate (UNII: 1Q73Q2JULR) (sodium cation - UNII:LYR4M0NH37)	sodium citrate	2.4 g in 150 g

Inactive Ingredients

Ingredient Name	Strength
calcium lactate (UNII: 2URQ2N32W3)	

sea salt (UNII: 87GE52P74G)

sodium sulfate (UNII: 0YPR65R21J)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60681-6001-1	1 in 1 CARTON		
1		150 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	12/19/1996	

Labeler - Sanum Kehlbeck GmbH & Co. KG (318386133)

Revised: 10/2009

Sanum Kehlbeck GmbH & Co. KG