## 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**

Active Ingredients	Purposes
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

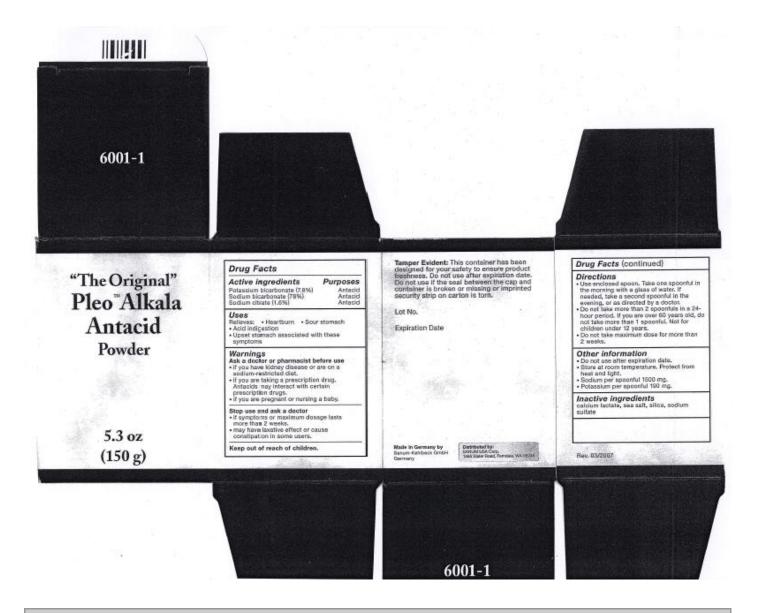
#### Distributed by:

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)



#### 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: 0 YPR65R21J)	

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