PLEO SANUVIS- lactic acid, l-Sanum Kehlbeck GmbH & Co. KG

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

PleoTM Sanuvis

Homeopathic Digestive Aid Lactic Acid

3.38 fl oz (100 mL)

INGREDIENTS

100mL solution contains L-Lactic acid (4X, 6X, 12X, 30X, 200X, in equal amounts), in a base of purified water, alcohol 12.4% by volume.

Tamper evident

Do not use this product if tamper-evident seal on base of bottle cap is missing or broken or if imprinted security strip on carton is torn.

DOSAGE

 $1-3 \times \text{daily } 5-20 \text{ drops.}$

WARNING

If symptoms persist more than a few days, contact a licensed practitioner. As with any other drug, if you are pregnant or nursing a baby, seek the advice of a health care professional before using this product.

Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Protect from light and heat.

Made in Germany

Distributed by:

SANUM USA Corp. 1465 Slater Road Ferndale, WA 98248

Manufactured By:

Sanum-Kehlbeck GmbH & Co. KG

Rev. 12/2007

PRINCIPAL DISPLAY PANEL - 100 mL Label

PleoTM Sanuvis

HOMEOPATHIC DIGESTIVE AID Lactic Acid

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Rev. 06/2009

750TR10PE100US906

Pleo[™] Sanuvis HOMEOPATHIC DIGESTIVE AID Lactic Acid

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ade in Germany for: ANUM USA Corp., 1465 Slater Road Arndale, WA 98248 A Sanum-Kehlbeck GmbH & Co. KG

PLEO SANUVIS

lactic acid, l- kit

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60681-6300

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:60681-6300-1	1 in 1 CARTON			
1		1 in 1 BOTTLE, DROPPER			

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		100
Part 2		100
Part 3		100
Part 4		100
Part 5		100

Part 1 of 5

LACTIC ACID, L-

lactic acid, l- solution

Product Information

Item Code (Source) NDC:60681-6300

Route of Administration ORAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
l	lactic acid. l- (UNII: F9S9FFU82N) (lactic acid. l UNII:F9S9FFU82N)	lactic acid. l-	4 [hp X] in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
alcohol (UNII: 3K9958V90M)			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		02/19/1997	

Part 2 of 5

LACTIC ACID, L-

lactic acid, l- solution

Product Information	
Item Code (Source)	NDC:60681-6300
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
lactic acid, l- (UNII: F9S9FFU82N) (lactic acid, l UNII:F9S9FFU82N)	lactic acid, l-	6 [hp_X] in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Unapproved homeopathic		02/19/1997		

Part 3 of 5

LACTIC ACID, L-

lactic acid, l- solution

Product Information Item Code (Source) NDC:60681-6300 Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
lactic acid, l- (UNII: F9S9FFU82N) (lactic acid, l UNII:F9S9FFU82N)	lactic acid, l-	12 [hp_X] in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
alcohol (UNII: 3K9958V90M)			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		02/19/1997	

Part 4 of 5

LACTIC ACID, L-

lactic acid, l- solution

Product Information

Item Code (Source) NDC:60681-6300

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient I	Name	Basis of Strength	Strength
lactic acid, l- (UNII: F9S9FFU82N) (lactic ac	id, l UNII:F9S9FFU82N)	lactic acid, l-	30 [hp_X] in 100 mL

Inactive Ingredients Ingredient Name Strength water (UNII: 059QF0KO0R)

alcohol (UNII: 3K9958V90M)

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateUnapproved homeopathic02/19/1997

Part 5 of 5

LACTIC ACID, L-

lactic acid, l- solution

Product Information		
Item Code (Source)	NDC:60681-6300	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
lactic acid, l- (UNII: F9S9FFU82N) (lactic acid, l UNII:F9S9FFU82N)	lactic acid, l-	200 [hp_X] in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		02/19/1997	
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		02/19/1997	

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

Revised: 10/2009 Sanum Kehlbeck GmbH & Co. KG