PLEO CAL- giant puffball solution/ drops 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.

Pleo™ Cal DROPS 3X

Homeopathic Medicine

Indications

To reduce bleeding from cuts and scrapes.

INGREDIENTS

10 mL Calvatia gigantea 3X in a base of purified water, ethanol (70%).

Tamper Evident

Use this product only if tamper evident strip has not been broken or removed from base of cap.

DOSAGE

5–10 drops, 1–3 times daily, before mealtime.

WARNING

If symptoms persist more than a few days, contact a licensed practitioner. As with any 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. 6/98

PRINCIPAL DISPLAY PANEL - 10 mL Label

PleoTM Cal DROPS 3X

Homeopathic Medicine

Indications: To reduce bleeding from cuts and scrapes.

0.34 fl oz (10 mL)

DOSAGE: 5–10 drops, 1–3 times daily before mealtime. **WARNING:** If symptoms persist more than a few days, contact a licensed practitioner. As with any 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. **TAMPER EVIDENT:** Do not use this product if tamper-evident seal on base of bottle cap is missing or broken. **INGREDIENTS:** 10 mL Calvatia gigantea 3X in a base of purified water, ethanol (70%). Rev. 06/2009

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Made in Germany for: SANUM USA Corp., 1465 Stater Road Ferndale, WA 98248 by Sanun-Kehlbeck GmbH & Co. KG

PRINCIPAL DISPLAY PANEL - 10 mL Box

PleoTM Cal DROPS 3X

249TR3XPE10US906

Homeopathic Medicine

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giant puffball solution/ drops

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60681-0111

Route of Administration ORAL

Active Ingredient/Active Moiety

:	Ingredient Name	Basis of Strength	Strength

GIANT PUFFBALL (UNII: 16839 Y031A) (GIANT PUFFBALL - UNII:16839 Y031A) GIANT PUFFBALL 3 [hp_X] in 10 mL

Inactive Ingredients

mactive ingredients					
Ingredient Name	Strength				
water (UNII: 059QF0KO0R)					
alcohol (UNII: 3K9958 V90 M)					

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:60681-0111-1	1 in 1 CARTON					
1		10 mL in 1 BOTTLE, DROPPER					

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		08/19/1998	

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

Revised: 9/2009 Sanum Kehlbeck GmbH & Co. KG