PLEO POLY OM- lactococcus lactis immunoserum rabbit, streptococcus pyogenes immunoserum rabbit, streptococcus viridans group immunoserum rabbit, staphylococcus epidermidis immunoserum rabbit, staphylococcus aureus immunoserum rabbit, streptococcus pneumoniae immunoserum rabbit, and mycobacterium bovis immunoserum rabbit 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.

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## Pleo® Poly Om DROPS 9X

Homeopathic Medicine 0.34 fl oz (10 mL)

#### **Indications**

skin conditions, such as warts and moles.

#### DOSAGE

Unless otherwise prescribed, apply 5-10 drops into the bend of the elbow and rub in three times daily.

#### **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 other medications out of the reach of children.** In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Protect from light and heat.

#### INGREDIENTS

10 mL aqueous dilution contains: antitoxins and antigens 9X of Streptococcus lacticus, -pyogenes, -haemolyticus, - viridans; Staphylococcus albus, -pharyngis, -aureus; Diplococcus lanceolatus; Mycobacterium tuberculosis typus bovinus.

Inactive Ingredient water

## **Tamper Evident**

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

Made in Germany

## Distributed by:

SANUM USA Corp.

1465 Slater Road

Ferndale, WA 98248

**Manufactured by:** 

Sanum-Kehlbeck GmbH & Co. KG Hoya, Germany

Rev. 05/2010

### PRINCIPAL DISPLAY PANEL - 10 mL Bottle Label

Pleo<sup>®</sup> Poly Om DROPS 9X (applied topically)

Homeopathic Medicine

**Indications**: skin conditions, such as warts and moles.

0.34 fl oz (10 mL)

**Dosage**: Unless otherwise prescribed, 5-10 drops into the bend of the elbow and rub in three times daily. **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 aqueous dilution contains: antitoxins and antigens 9X of Streptococcus lacticus, -pyogenes, -haemolyticus, -viridans; Staphylococcus albus, -pharyngis, -aureus; Diplococcus lanceolatus; Mycobacterium tuberculosis typus bovinus. Rev. 05/2010

## Pleo® Poly Om DROPS 9X (applied topically)

Homeopathic Medicine

Indications: skin conditions, such as warts and moles.

## 0.34 fl oz (10 mL)

Dosage: Unless otherwise prescribed, 5-10 drops into the bend of the elbow and rub in three times daily. 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 aqueous dilution contains: antitoxins and antigens 9X of Streptococcus lacticus, -pyogenes, -haemolyticus, -viridans; Staphylococcus albus, -pharyngis, -aureus; Diplococcus lanceolatus; Mycobacterium tuberculosis typus bovinus. Rev. 05/2010

Road, Ferndale, WA 98248 Made in Germany for:

### PLEO POLY OM

lactococcus lactis immunoserum rabbit, streptococcus pyogenes immunoserum rabbit, streptococcus viridans group immunoserum rabbit, staphylococcus epidermidis immunoserum rabbit, staphylococcus aureus immunoserum rabbit, streptococcus pneumoniae immunoserum rabbit, and mycobacterium bovis immunoserum rabbit solution/ drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60681-2808	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
lactococcus lactis immunoserum rabbit (UNII: AST1Y049U1) (lactococcus lactis immunoserum rabbit - UNII:AST1Y049U1)	lactococcus lactis immunoserum rabbit	9 [hp_X] in 10 mL			
streptococcus pyogenes immunoserum rabbit (UNII: 726RS6QMS8) (streptococcus pyogenes immunoserum rabbit - UNII:726RS6QMS8)	streptococcus pyogenes immunoserum rabbit	9 [hp_X] in 10 mL			
streptococcus viridans group immunoserum rabbit (UNII: 4U4OEA495W) (streptococcus viridans group immunoserum rabbit - UNII:4U4OEA495W)	streptococcus viridans group immunoserum rabbit	9 [hp_X] in 10 mL			
staphylococcus epidermidis immunoserum rabbit (UNII: 8409DJA34Y) (staphylococcus epidermidis immunoserum rabbit - UNII:8409DJA34Y)	staphylococcus epidermidis immunoserum rabbit	9 [hp_X] in 10 mL			
staphylococcus aureus immunoserum rabbit (UNII: Q1G8TGQ05J) (staphylococcus aureus immunoserum rabbit - UNII:Q1G8TGQ05J)	staphylococcus aureus immunoserum rabbit	9 [hp_X] in 10 mL			
streptococcus pneumoniae immunoserum rabbit (UNII: IWJ46H2H5C) (streptococcus pneumoniae immunoserum rabbit - UNII:IWJ46H2H5C)	streptococcus pneumoniae immunoserum rabbit	9 [hp_X] in 10 mL			
<b>mycobacterium bovis immunoserum rabbit</b> (UNII: NNW4543CRP) (mycobacterium bovis immunoserum rabbit - UNII:NNW4543CRP)	mycobacterium bovis immunoserum rabbit	9 [hp_X] in 10 mL			

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

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:60681-2808-1	1 in 1 CARTON			
1	10 mL in 1 BOTTLE, DROPPER			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	<b>Marketing Start Date</b>	Marketing End Date		
UNAPPROVED HOMEOPATHIC		04/07/1999			

# $\boldsymbol{Labeler} \text{ - } \textbf{Sanum Kehlbeck GmbH \& Co. KG (318386133)}$

Revised: 10/2010 Sanum Kehlbeck GmbH & Co. KG