ARNICA MONTANA- arnica montana tablet Rxhomeo Private Limited d.b.a. Rxhomeo, Inc

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.

ACTIVE INGREDIENT

ARNICA MONTANA HPUS 3X and Higher

USES

Bruises, Aches, Pains

INDICATIONS

Condition listed above or as directed by the physician

DOSAGE

Adults- Take 4 or 6 Tablets by mouth, three times daily or as suggested by physician. Children 2 years and older- take 1/2 the adult dose.

WARNINGS

This product is to be used for self-limiting conditions

If symptoms do not improve in 4 days, or worsen, discontinue use and seek assistance of health professional

As with any drug, if you are pregnant, or nursing a baby, seek professional advice before taking this product

Keep this and all medication out of reach of children

Do not use if capseal is broken or missing.

Close the cap tightly after use.

INACTIVE INGREDIENTS

Lactose

STORAGE

Store in a cool dark place

QUESTIONS OR COMMENTS

 $www.Rxhomeo.com \,|\, 1.888.2796642 \,|\, info@rxhomeo.com$

Rxhomeo, Inc 9415 Burnet Road, Suite 312, Austin, TX 78758

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



ARNICA MONTANA 3X



Ictured according to the Homoeopathic narmacopoela of the United States Est.# 30052969310

HOMEOPATHIC MEDICINE

Ingredients: Active: As Above, Inactive: Lactose USES: Bruises, Aches, Pains

Dosage: Adults-Take 4 or 6 tablets by mouth, three times daily or as directed by physician. Children 2 years and older -Take 1/2 the adult dose. Warnings: This product is to be used for self-limiting conditions. If symptoms do not improve in 4 days, or worsen, discontinue use and seek assistance of a health professional * As with any drug, if you are pregnant or nursing a baby, seek professional advice before taking this product * Keep this and all medication out of reach of children * Store in a cool dark place Do not use if capseal is broken or missing * Close cap tightly after use.



Distributed in the US by Rxhomeo, Inc 9415 Burnet Road, Suite 312, Austin, TX 78758 Manufactured by: Rxhomeo Private Limited "Indradhanush", 4-1-424 to 426, Bank Street, Abids, Hyderabad #500001 India.

NDC 15631-0521-3 B.No XXXXXXXXXX MFD XX/XX EXP XX/XX Contents 100 Tablets

ARNICA MONTANA

arnica montana tablet

\mathbf{r}		1 .	T (. •
ν	rn	duct	Into	rma	tinn.
_	1 U	uuct	11110	1 IIIu	uvii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15631-0521

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW) ARNICA MONTANA 3 [hp_X]

Inactive Ingredients

Ingredient Name Strength

LACTOSE (UNII: J2B2A4N98G)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	3mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15631-0521- 0	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:15631-0521-1	4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:15631-0521-2	50 in 1 CONTAINER; Type 0: Not a Combination Product		
4	NDC:15631-0521-3	100 in 1 CONTAINER; Type 0: Not a Combination Product		
5	NDC:15631-0521-4	250 in 1 CONTAINER; Type 0: Not a Combination Product		

	6 NDC:15631-0521-	5 500 in 1 CONTAINER; Type 0: Not a Combination Product
П	NDC:15631-0521-6	1000 in 1 CONTAINER; Type 0: Not a Combination Product
	NDC:15631-0521-	7 10000 in 1 CONTAINER; Type 0: Not a Combination Product

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved homeopathic		12/30/2015			

Labeler - Rxhomeo Private Limited d.b.a. Rxhomeo, Inc (650833994)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rxhomeo, Inc		832534981	wholesale drug distributor(15631-0521)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Rxhomeo Private Limited d.b.a. Rxhomeo, Inc		650833994	manufacture(15631-0521), label(15631-0521)	

Revised: 12/2015 Rxhomeo Private Limited d.b.a. Rxhomeo, Inc