BERBERIS VULGARIS- berberis vulgaris pellet
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

BERBERIS VULGARIS HPUS 1X and higher

USES

USES: Temporary Relief - Chest Congestion*

* Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

INDICATIONS

Condition listed above or as directed by the physician

DOSAGE

Adults- Take 4 or 6 Pellets 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 preganant, 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

Sucrose

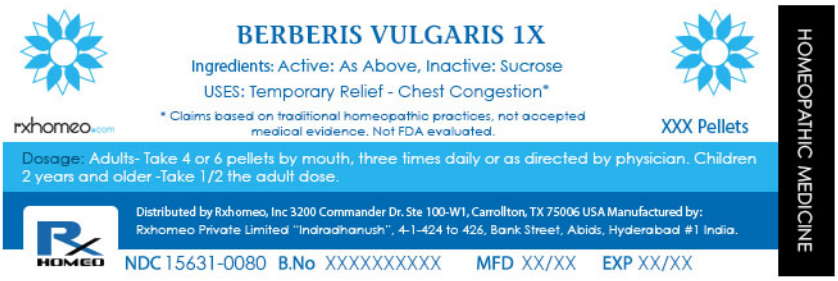
STORAGE

Store in a cool dark place

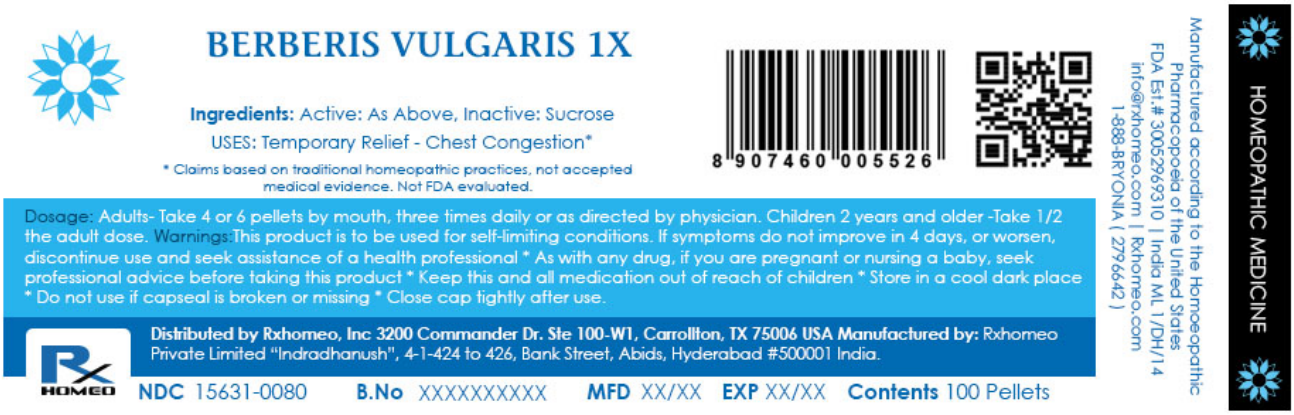
QUESTIONS OR COMMENTS

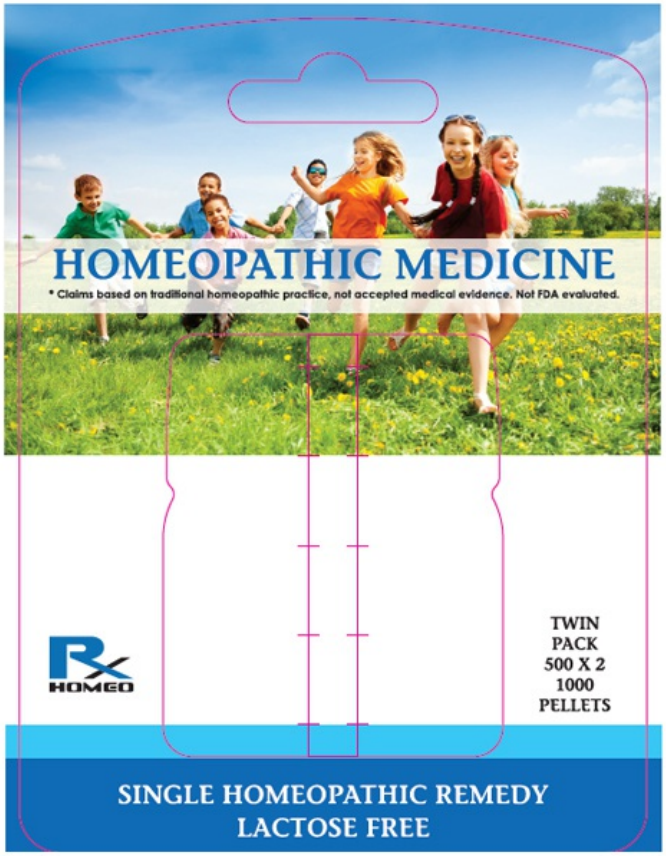
www.Rxhomeo.com | 1.888.2796642 | info@rxhomeo.com

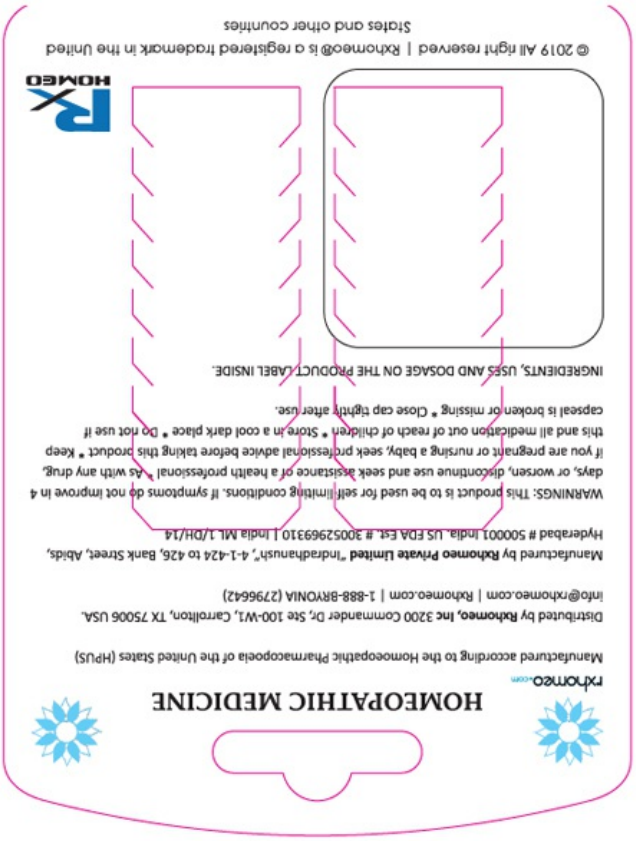
Rxhomeo, Inc 3200 Commander Dr, Ste 100-W1, Carrollton, TX 75006 USA



<<< MINI LABEL USED WITH BLISTER PACK FOR SELECT PACK SIZES







NOTES RELATED TO PACKING
1. All labels and secondary packing specimens have our India address as the manufacturer, but if the product is manufactured by some other manufacturer, the manufacturers name and address will be changed or removed if those attributes are confidentail. However, the manufacturers US FDA Establishment number will be printed at all times.
2. Primary Packing > Depending on the pack size/contents, a bottle/container of appropriate size will be used. Depending on the bottle/container size, a label of appropriate size will be used i.e. regular size or mini size.
3. Secondary Packing > If the bottle/container is small, we will use a secondary packing i.e a Carton box or a Blister pack.

BERBERIS VULGARIS

berberis vulgaris pellet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15631-0080
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	1 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15631-0080-0	100 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2018	
2	NDC:15631-0080-1	200 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2018	
3	NDC:15631-0080-2	400 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2018	
4	NDC:15631-0080-3	750 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2018	
5	NDC:15631-0080-4	2500 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2018	
6	NDC:15631-0080-5	12500 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2018	
7	NDC:15631-0080-6	500 in 1 PACKAGE; Type 0: Not a Combination Product	08/23/2021	
8	NDC:15631-0080-7	1000 in 1 PACKAGE; Type 0: Not a Combination Product	08/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/12/2015	

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

Establishment

Name	Address	ID/FEI	Business Operations
Rxhomeo Private Limited d.b.a. Rxhomeo, Inc		650833994	manufacture(15631-0080) , label(15631-0080)