CALCAREA PHOSPHORICA- calcarea phosphorica tablet, chewable HOMEOLAB USA 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.

DRUGS FACTS

Active ingredients HPUS

Calcarea phosphorica (Calcium phosphate) 6X

Purpose

......Teething and tooth pain, bone pain, rheumatic pain, sore throat

The letters 'HPUS' indicate that the component in this product is officially monographed in the Homoeopathic Pharmacopoeia of the United States.

Uses

This tissue salt helps relieve teething pain, tooth pain, bone pain, rheumatic pain and sore throat.*

*These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice.

Warnings

Stop use and ask a doctor if symptoms persist for more than 7 days or worsen.

As with any drug, ask a doctor before use if pregnant or nursing.

Keep this and all medications out of the reach of children.

In case of emergency or accidental overdose, contact a medical professional or a Poison Control Center immediately.

Directions

<u>Children from 2 to 5 years:</u> Crush 2 tablets and dissolve in water 3 times daily, or as directed by a healthcare professional.

Adults and children over 5 years: Chew 2 tablets 3 times daily, or as directed by a healthcare professional.

- Do not use more than directed.
- Do not take with food.

Other information

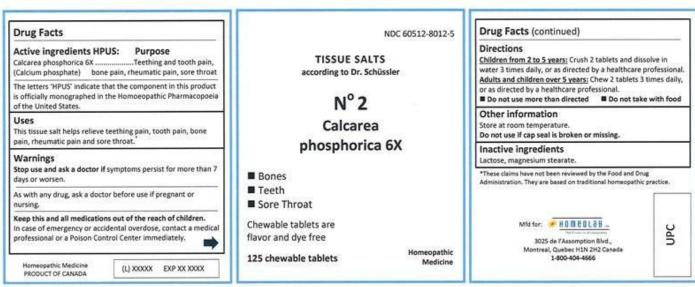
Store at room temperature.

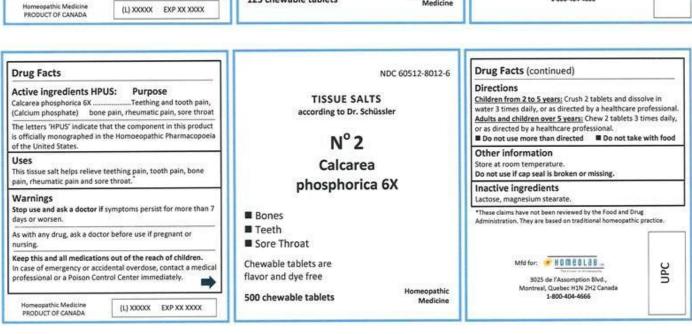
Do not use if cap seal is broken or missing.

Inactive ingredients

Lactose, magnesium stearate.

LABEL





CALCAREA PHOSPHORICA calcarea phosphorica tablet, chewable **Product Information** HUMAN OTC DRUG NDC:60512-8012 Product Type Item Code (Source) ORAL Route of Administration Active Ingredient/Active Moiety **Ingredient Name Basis of Strength** Strength CALCIUM PHO SPHATE (UNII: 97Z1WI3NDX) (CALCIUM CATION - UNII:2M83C4R6ZB) **CALCIUM PHO SPHATE** 6 [hp_X]

Inactive Ingredients		
Ingredient Name	Strength	
LACTO SE MO NO HYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	8 m m
Flavor		Imprint Code	NONE
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:60512-8012-5	125 in 1 JAR		
2 NDC:60512-8012-6	500 in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/13/2014	

Labeler - HOMEOLAB USA INC (202032533)

Establishment			
Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC		202032533	manufacture(60512-8012)

Revised: 3/2014 HOMEOLAB USA INC