

TINNI-CALM- carboneum, sulphuratum, chamomilla, chininum, sulphuricum, salicylicum acidum, silicea oil

Silver Star Brands

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.

Healthful™ Naturals Tinni-Calm

HPUS Active Ingredients

HPUS Active Ingredients: Each does contains equal volumes of: Carboneum sulphuratum, Chamomilla, Chininum sulphuricum, Salicylicum acidicum, Silicea.

Uses†

Uses†: For symptomatic treatment of ringing, buzzing, undesirable noises, and general discomfort in the ears.

† as per various homeopathic materia medicas. These uses have not been evaluated by the FD, and product has not been clinically tested.

Warnings

Warnings: For external use only. If symptoms persist or worsen, discontinue use immediately and consult a healthcare professional. If pregnant or breastfeeding, ask a health professional before use. Keep this and all medication out of reach of children. Avoid using near eyes or mouth. If swallowed, get medical help or contact a Poison Control Center immediately.

Discontinue use if irritation or reaction occurs.

Directions

Directions: Shake well before using. Use at first sign of symptoms. Dispense a small amount into hands. Massage gently onto cartilage of outer ear canal and outer nostrils. Inhale deeply and slowly maintaining stillness. Repeat as needed.

FOR EXTERNAL USE ONLY

Keep carton for additional drug facts and information.

Tamper resistant for your protection.

Use only if safety seal is intact.

Inactive Ingredients

Inactive Ingredients: Grapeseed oil, ginger essential oil, cypress essential oil, grapefruit essential oil, lemon essential oil.

Keep this and all medication out of reach of children.

If pregnant or breastfeeding, ask a health professional before use.

Temporarily soothes symptoms associated with ringing in the ears.

Drug Facts (continued)

Warnings: For external use only. If symptoms persist or worsen, discontinue use immediately and consult a healthcare professional. If pregnant or breastfeeding, ask a health professional before use. Keep this and all medication out of reach of children. Avoid using near eyes or mouth. If swallowed, get medical help or contact a Poison Control Center immediately. Discontinue use if irritation or reaction occurs.

Distributed by Silver Star Brands
Oshkosh, WI 54906 | 1-800-308-1384
SKU# 357960



Homeopathic Formula

NDC# 68703-212-30



Tinni-Calm

Temporarily soothes
symptoms associated with
ringing in the ears

1 fl oz (30 mL)

Drug Facts

HPUS Active Ingredients: Each dose contains equal volumes of: Carboneum sulphuratum, Chamomilla, Chininum sulphuricum, Salicylicum acidum, Silicea.

Uses†: For symptomatic treatment of ringing, buzzing, undesirable noises, and general discomfort in the ears.

Directions: Shake well before using. Use at first sign of symptoms. Dispense a small amount into hands. Massage gently onto cartilage of outer ear canal and outer nostrils. Inhale deeply and slowly, maintaining stillness. Repeat as needed.

For external use only

† as per various homeopathic materia medicas. These uses have not been evaluated by the FDA, and product has not been clinically tested.

Keep carton for additional drug facts and information.

Tamper resistant for your protection.
Use only if safety seal is intact.



Tinni-Calm

Homeopathic Formula

NDC# 68703-212-30



Tinni-Calm

Temporarily soothes symptoms associated with occasional ringing, buzzing, undesirable noises, and general discomfort in the ears

1 fl oz (30 mL)

FOR EXTERNAL USE ONLY

Keep carton for complete drug facts & product information.

FOR EXTERNAL USE ONLY

- Safe, effective homeopathic remedy
- Supports health & balance in the ear
- Soothes occasional ringing & buzzing sounds in the ears
- Helps reduce ear discomfort
- May assist in reducing undesirable noise in the ear, potentially improving hearing clarity

Tamper resistant for your protection. Use only if safety seal is intact.



Dist. by Silver Star Brands
Oshkosh, WI 54906
1-800-308-1384

SKU# 357960 SSB01

Drug Facts (continued)

Uses†: For symptomatic treatment of ringing, buzzing, undesirable noises, and general discomfort in the ears.

† As per various homeopathic materia medicas. These uses have not been evaluated by the FDA, and product has not been clinically tested.

Directions:

- Shake well before using.
- Dispense a small amount into hands.
- Massage gently onto cartilage of outer ear canal and outer nostrils.
- Inhale deeply and slowly, maintaining stillness.
- Repeat as needed.

Warnings:

- If symptoms persist or worsen, discontinue use immediately and consult a healthcare professional.
- If pregnant or breast-feeding, ask a health care professional before use.
- Keep out of reach of children.
- For external use only.
- Avoid using near eyes or mouth.
- If swallowed, get medical help or contact a Poison Control Center immediately.
- Some individuals may be sensitive to essential oils. If irritation or reaction occurs, discontinue use.

Drug Facts

HPUS* Active Ingredients Purpose†
Equal volumes of each ingredient as follows:

Carboneum sulphuratum (6C)	Buzzing, ringing
Chamomilla (6C)	Calming, inflammation
Chininum sulphuricum (6C)	Ringing, roaring
Salicylicum acidum (6C)	Undesirable noise
Silicea (30C)	Ringing, inflammation

*"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Inactive Ingredients:

Grapeseed oil, ginger essential oil, cypress essential oil, grapefruit essential oil, lemon essential oil.

Other information:

Intended to complement, not replace, standard medical care.

carboneum, sulphuratum, chamomilla, chininum, sulphuricum, salicylicum acidum, silicea oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68703-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBON DISULFIDE (UNII: S54S8B99E8) (CARBON DISULFIDE - UNII:S54S8B99E8)	CARBON DISULFIDE	6 [hp_C] in 30 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	30 [hp_C] in 30 mL
HYDROQUININE SULFATE (UNII: F507371PJA) (HYDROQUININE - UNII:31J3Q51T6L)	HYDROQUININE SULFATE	6 [hp_C] in 30 mL
MAGNESIUM SALICYLATE (UNII: 41728CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	6 [hp_C] in 30 mL
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER) (MATRICARIA CHAMOMILLA FLOWERING TOP OIL - UNII:SA8AR2W4ER)	MATRICARIA CHAMOMILLA FLOWERING TOP OIL	6 [hp_C] in 30 mL

Inactive Ingredients

Ingredient Name	Strength
GRAPEFRUIT (UNII: O82C39RR8C)	
LEMON OIL (UNII: I9GRO824LL)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
GINGER OIL (UNII: SAS9Z1SVUK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68703-212-30	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	12/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/14/2016	

Labeler - Silver Star Brands (006070379)

Registrant - Silver Star Brands (006070379)

Establishment

Name	Address	ID/FEI	Business Operations
Vitality Works		137752817	manufacture(68703-212)

