

**TONSIN- allium cepa, pulsatilla pratensis, sambucus nigra, ferrum phosphoricum, hepar sulphuris, kali muriaticum, natrum muriaticum, kali bichromicum, mercurius solubis tablet
PRIVATE LABEL BRANDS CC**

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 INGREDIENTS (OTC- ACTIVE INGREDIENT SECTION)

Allium cepa D3 HPUS

Pulsatilla Pratensis D3 HPUS

Sambucus nigra D3 HPUS

Ferrum Phosphoricum D6 HPUS

Hepar Sulphuris D6 HPUS

Kali Muriaticum D6 HPUS

Natrum Muriaticum D6 HPUS

Kali Bichromicum D6 HPUS

Mercurius Solubis D10 HPUS

PURPOSE (DOSAGE & ADMINISTRATION SECTION)

Temporarily relieves sneezing and watery nasal discharge

Temporarily relieves colds with loss of taste and smell

Temporarily relieves colds and easing mucus production reducing swelling in nasal passages

Temporarily relieves colds, runny nose, inflammation of sinus passages and throat

Temporarily relieves runny then stuffy nose with thick slimy mucus

Temporarily relieves sinusitis, earache, and sore throat

Temporarily relieves sneezing, tickling in throat loss of taste and smell

Temporarily relieves thick green/ yellow nasal discharge and glue ear

Temporarily relieves colds, ear, eye infections and sore throat

USES (OTC- PURPOSE SECTION)

Temporarily relieves symptoms associated with sinusitis, hay fever and colds. Such as: sneezing, runny nose, mucus, and minor sore throat.

KEEP OUT OF REACH OF CHILDREN (OTC- KEEP OUT OF REACH OF CHILDREN SECTION)

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS (INDICATIONS & USAGE SECTION)

Adults and children aged 12 years or older:

Dissolve 2 tablets in mouth 3x daily. May be taken hourly in acute cases

Children between 2 and 12 years old:

Dissolve 1 tablet in mouth 3x daily. May be taken hourly in acute cases.

Infants: 1 crushed tablet diluted in cooled, boiled, water.

OTHER INFORMATION (INSTRUCTIONS FOR USE SECTION)

Store below 77°F and away from direct sunlight.

WARNING (WARNINGS SECTION)

These tablets contain lactose and should be used with caution by individuals with a severe sensitivity or intolerance to lactose as well as diabetics.

STOP USE AND ASK DOCTOR IF (OTC- STOP USE SECTION)

if symptoms persist for more than 3 days or worsen or if sore throat persists for more than 2 days or occurs with a fever, headache, rash, nausea or vomiting.

ASK A DOCTOR (OTC- ASK DOCTOR SECTION)

ASK A DOCTOR BEFORE USING IN CHILDREN UNDER 3 YEARS OF AGE

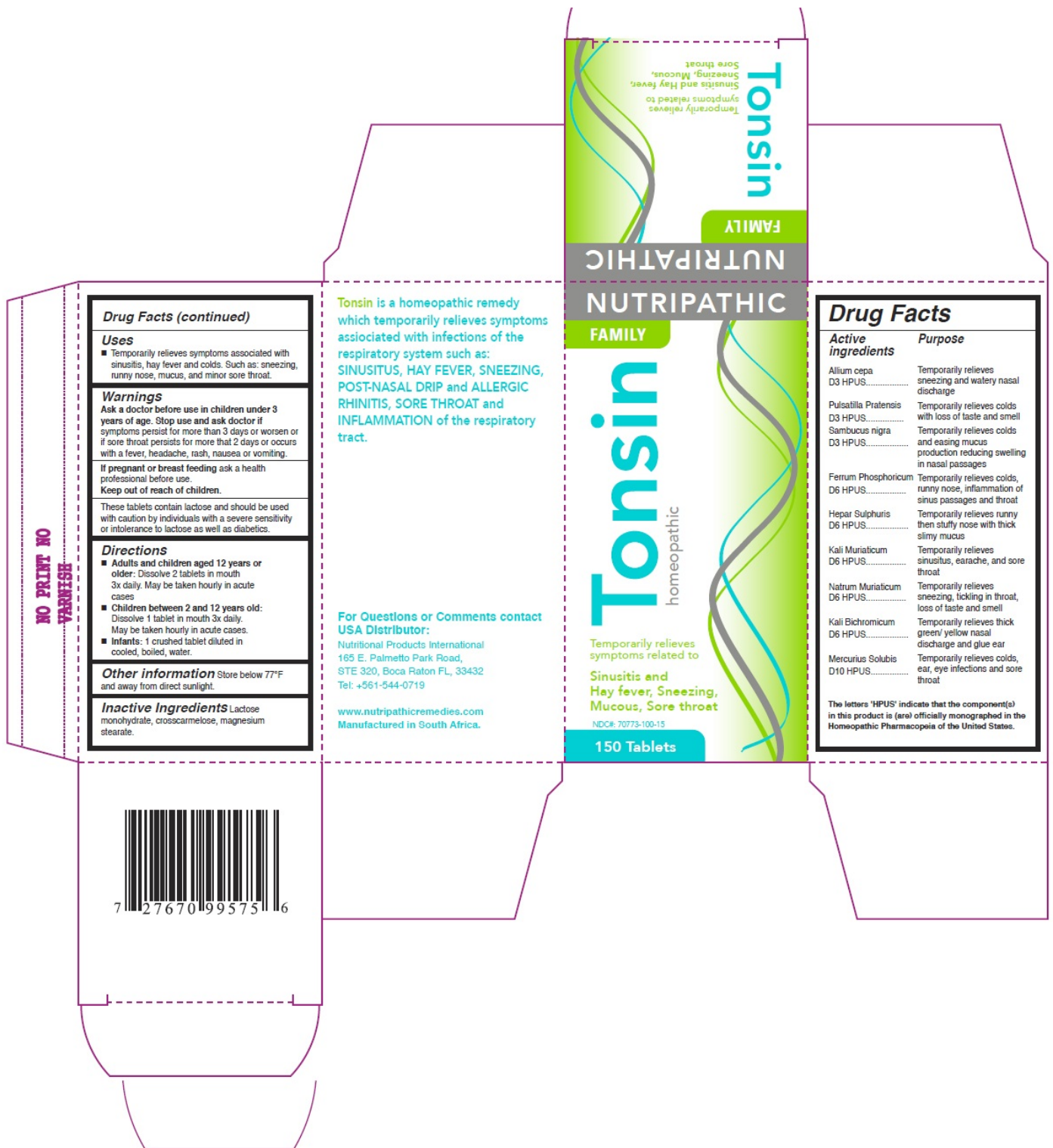
IF PREGNANT OR BREASTFEEDING, (OTC- PREGNANCY OR BREAST FEEDING SECTION)

ask a health professional before use.

INACTIVE INGREDIENTS (INACTIVE INGREDIENT SECTION)

Lactose monohydrate, croscarmellose, magnesium stearate.

Principle Display Panel- 150 tablet container



TONSIN

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70773-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	3 [hp_X] in 100 [hp_X]
FERRUM PHOSPHORICUM (UNII: 91GQH8I5F7) (FERRUM PHOSPHORICUM - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	6 [hp_X] in 100 [hp_X]
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 100 [hp_X]
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	6 [hp_X] in 100 [hp_X]
ALLIUM CEPA WHOLE (UNII: 8P2VLG2456) (ALLIUM CEPA WHOLE - UNII:8P2VLG2456)	ALLIUM CEPA WHOLE	3 [hp_X] in 100 [hp_X]
PULSATILLA PRATENSIS (UNII: 8E272251DI) (PULSATILLA PRATENSIS - UNII:8E272251DI)	PULSATILLA PRATENSIS	3 [hp_X] in 100 [hp_X]
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 100 [hp_X]
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	6 [hp_X] in 100 [hp_X]
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	10 [hp_X] in 100 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELOSE (UNII: 029TFK992N)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70773-100-15	1 in 1 CARTON	12/25/2017	
1		1 [hp_X] in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/25/2017	

Labeler - PRIVATE LABEL BRANDS CC (539043103)**Registrant** - PRIVATE LABEL BRANDS CC (539043103)

Establishment

Name	Address	ID/FEI	Business Operations
Herbal and Homeopathic (Pty) Ltd.		638215520	manufacture(70773-100)

Revised: 12/2017

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