BACTO PLUS- baptis ia tinctoria, echinacea (angustifolia), phytolacca decandra, aconitum napellus, arsenicum album, belladonna, ferrum phosphoricum, laches is mutus, phosphorus liquid

Dr. Elena M. Morreale

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.

Drug Facts:

ACTIVE INGREDIENTS:

Baptisia tinctoria 3X, Echinacea (Angustifolia) 3X, Phytolacca decandra 3X, Aconitum napellus 12X, Arsenicum album 12X, Belladonna 12X, Ferrum phosphoricum 12X, Lachesis mutus 12X, Phosphorus 12X.

INDICATIONS:

For temporary relief of fever, irritated throat, and acute irritation of the bladder.

WARNINGS:

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use if tamper evident seal is broken or missing.

Store in a cool, dry place.

WARNING: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a physician promptly. Do not use more than two days or administer to children under 3 years of age unless directed by physician.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

For temporary relief of fever, irritated throat, and acute irritation of the bladder.

INACTIVE INGREDIENTS:

Demineralized Water, 20% Ethanol

QUESTIONS:

Dist. by Dr. Elena M. Morreale 10031 N. Dale Mabry Hwy.

Ste. A

Tampa, FL 33618

www.drelenamorreale.com

PACKAGE LABEL DISPLAY:

Dr. Elena M. Morreale

Chiropractic Physician

BACTO PLUS

Homeopathic Remedy

1 fl. oz. (30 ml)

WARNINGS: If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Do not use if tamper evident seal is broken or missing. Store in a cool, dry place.

INDICATIONS: For temporary relief of fever, irritated throat, and acute irritation of the bladder.

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LOT:



BACTO PLUS

Homeopathic Remedy

ACTIVE INGREDIENTS: Baptisia Tinctoria 3X, Echinacea 3X, Phytolacca Decandra 3X, Aconitum Napellus 12X, Arsenicum Album 12X, Belladonna 12X, Ferrum Phosphoricum 12X, Lachesis Mutus 12X, Phosphorus 12X.

INACTIVE INGREDIENTS: Demineralized water, 20% Ethanol 1 fl. oz. (30 ml) DIRECTIONS: Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist, consult your health care professional. Consult a physician for use in children under 12 years of age.

WARNING: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a physician promptly. Do not use more than two days or administer to children under 3 years of age unless directed by physician.

BACTO PLUS

baptisia tinctoria, echinacea (angustifolia), phytolacca decandra, aconitum napellus, arsenicum album, belladonna, ferrum phosphoricum, lachesis mutus, phosphorus liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50813-0006
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BAPTISIA TINCTORIA ROOT (UNII: 5EF0 HWI5WU) (BAPTISIA TINCTORIA ROOT -	BAPTISIA TINCTORIA	3 [hp_X]		

UNII:5EF0 HWI5WU)	ROOT	in 1 mL
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII: VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	3 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	3 [hp_X] in 1 mL
ACONITUM NAPELLUS (UNII: U0 NQ8555JD) (ACONITUM NAPELLUS - UNII: U0 NQ8555JD)	ACONITUM NAPELLUS	12 [hp_X] in 1 mL
ARSENIC TRIO XIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	12 [hp_X] in 1 mL
FERRUM PHO SPHO RICUM (UNII: 91GQH815F7) (FERROSOFERRIC PHOSPHATE - UNII: 91GQH815F7)	FERRUM PHOS PHORICUM	12 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII: VSW71SS07I)	LACHESIS MUTA VENOM	12 [hp_X] in 1 mL
PHO SPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

]	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:50813-0006-1	30 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/02/2014	

Labeler - Dr. Elena M. Morreale (826038759)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	$\label{eq:manufacture} \verb manufacture (50813-0006) , api manufacture (50813-0006) , label (50813-0006) , pack (50813-0006) $

Revised: 1/2015 Dr. Elena M. Morreale