

REHYDRATE JR.- avena sativa, equisetum hyemale, hypericum perforatum, ulmus fulva, glycyrrhiza glabra, glycyrrhiza glabra, pueraria lobata, aqua sulis, carlsbad aqua, adenosinum triphosphoricum dinatrum, germanium sesquioxide, hydrogen, oxygenium, wiesbaden liquid ParaDocs All Natural, 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.

Drug Facts:

ACTIVE INGREDIENTS:

Avena Sativa 3X, Equisetum Hyemale 4X, Hypericum Perforatum 6X, Ulmus Fulva 6X, Glycyrrhiza Glabra 12X, Pueraria Lobata 12X, Aqua Sulis 12C, Carlsbad Aqua 12C, Adenosinum Triphosphoricum Dinatrum 30C, Germanium Sesquioxide 30C, Hydrogen 3C, Oxygenium 30C, Wiesbaden 30C.

INDICATIONS:

To aid with proper hydration.

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.

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:

One drop per ounce of pure water. Consult a physician for use in children under 6 years of age.

INDICATIONS:

To aid with proper hydration.

INACTIVE INGREDIENTS:

Demineralized Water, Ethanol 1%, Glycerin, Proprietary Extract Blend of Beet (Root), Blessed Thistle (Aerial Parts), Boldo (Leaf), Celandine (Aerial Parts), Dandelion (Root), Parsley (Leaf).

QUESTIONS:

MFD. FOR:

ParaDocs All Natural Inc.

2640 E. Oakland Park Blvd.

Ft. Lauderdale, FL 33306

PACKAGE LABEL DISPLAY:

ReHydrateJr.

Homeopathic

2 FL OZ (60 ml)

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Homeopathic

1% Ethanol
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LOT:

REHYDRATE JR.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54638-0004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	3 [hp_X] in 1 mL
EQUISETUM HYEMALE (UNII: 59677RXH25) (EQUISETUM HYEMALE - UNII:59677RXH25)	EQUISETUM HYEMALE	4 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 1 mL
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q) (ULMUS RUBRA BARK - UNII:91QY4PXU8Q)	ULMUS RUBRA BARK	6 [hp_X] in 1 mL
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) (GLYCYRRHIZA GLABRA - UNII:2788Z9758H)	GLYCYRRHIZA GLABRA	12 [hp_X] in 1 mL

PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C) (PUERARIA MONTANA VAR. LOBATA ROOT - UNII:PET93F4I3C)	PUERARIA MONTANA VAR. LOBATA ROOT	12 [hp_X] in 1 mL
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	12 [hp_C] in 1 mL
ADENOSINE TRIPHOSPHATE DISODIUM (UNII: 5L51B4DR1G) (ADENOSINE TRIPHOSPHATE - UNII:8L70Q75FXE)	ADENOSINE TRIPHOSPHATE DISODIUM	30 [hp_C] in 1 mL
GERMANIUM SESQUIOXIDE (UNII: 96WE91N25T) (GERMANIUM SESQUIOXIDE - UNII:96WE91N25T)	GERMANIUM SESQUIOXIDE	30 [hp_C] in 1 mL
HYDROGEN (UNII: 7YNJ3PO35Z) (HYDROGEN - UNII:7YNJ3PO35Z)	HYDROGEN	30 [hp_C] in 1 mL
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	30 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BEET (UNII: N487KM8COK)	
CENTAUREA BENEDICTA FLOWERING TOP (UNII: NJN80GZ34N)	
PEUMUS BOLDUS LEAF (UNII: Q4EWM09M3O)	
CHELIDONIUM MAJUS FLOWERING TOP (UNII: O9HP59XU7F)	
TARAXACUM OFFICINALE ROOT (UNII: 9DE5YCO0RU)	
PARSLEY (UNII: 58FMD0Q0EV)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54638-0004-1	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/11/2020	

Labeler - ParaDocs All Natural, Inc. (008540744)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(54638-0004) , api manufacture(54638-0004) , label(54638-0004) , pack(54638-0004)