REMEDIENT- ascorbic acid, cholecalciferol, folic acid, cyanocobalamin, calcium citrate, iron protein succinylate, magnesium glycinate glutamine chelate, magnesium oxide, zinc, zinc-l carnosine complex, l-carnosine capsule

Levins Pharmaceuticals, LLC

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Remedient<sup>TM</sup>



## Remedient<sup>TM</sup> Capsules Dietary Supplement

## Dispensed by Prescription†

Acid-lowering medications can increase pH in the stomach and small intestine, leading to decreased absorption of key vitamins and minerals. Remedient $^{TM}$  is an orally administered prescription vitamin formulation designed to replete these key vitamins and minerals and help support gastro-esophageal health.  $\dagger$ †

†This product is a prescription- folic acid with or without other dietary ingredients that – due to increased folic acid levels increased risk associated with masking of B12

deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760). The most appropriate way to ensure pedigree

reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription (Rx). This is not an Orange Book product.

This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

- 1. Federal Register Notice of August 2, 1973 (38 FR 20750
- 2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
- 3. Federal Register Notice of March 5, 1996 (61 FR 8760)
- †† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

Remedient<sup>TM</sup> capsules should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

Usual adult dose is one (1) capsule once or twice daily or as prescribed by a licensed medical practitioner. Remedient<sup>TM</sup> should be taken on an empty stomach for optimal absorption.

Remedient<sup>TM</sup> capsules are supplied as (purple and white, oblong-shaped) capsules in a child-resistant bottle of 30-count ("71905-0102-30"\*\*).

\*\*Levins Pharmaceuticals does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

## KEEP OUT OF REACH OF CHILDREN

**Tamper evident:** Do not use if seal is broken or missing

To report adverse events or to obtain product information, contact 228-392-0043.

## REMEDIENT

ascorbic acid, cholecalciferol, folic acid, cyanocobalamin, calcium citrate, iron protein succinylate, magnesium glycinate glutamine chelate, magnesium oxide, zinc, zinc-l carnosine complex, l-carnosine capsule

Product Information					
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:71905-102		
Route of Administration	ORAL				

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	200 mg			
Vitamin D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	Vitamin D	20 ug			
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1667 ug			
CYANO CO BALAMIN (UNII: P6 YC3EG204) (CYANOCO BALAMIN - UNII:P6 YC3EG204)	CYANOCOBALAMIN	6 ug			
CALCIUM CITRATE (UNII: MLM29 U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	40 mg			
IRON PROTEIN SUCCINYLATE (UNII: VBJ9L90P4L) (IRON PROTEIN SUCCINYLATE - UNII: VBJ9L90P4L)	IRON PROTEIN SUCCINYLATE	3.6 mg			
MAGNESIUM GLYCINATE (UNII: IFN18 A4Y6B) (MAGNESIUM CATION - UNII:T6 V3LHY8 38)	MAGNES IUM GLYCINATE	8.5 mg			
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G) (MAGNESIUM CATION - UNII:T6 V3LHY838)	MAGNES IUM O XIDE	60.3 mg			
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	8 mg			
POLAPREZINC (UNII: 0 WA1B15A1Z) (POLAPREZINC - UNII:0 WA1B15A1Z)	POLAPREZINC	37.5 mg			
CARNO SINE (UNII: 8 HO6 PVN24W) (CARNOS INE - UNII: 8 HO6 PVN24W)	CARNOSINE	28 mg			

Packaging						
# Item Code	Package Description	Marketii	ng Start Date	Marketing End Date		
1 NHRIC:71905-102-30	30 in 1 BOTTLE					
Marketing Information						
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start D	Date Marketing End Da		
dietary supplement			07/19/2019			

Supplement Facts					
Serving Size:		Serving per Container :			
An	nount Per Serving	% Daily Value			
color					
color					
shape					
size (solid drugs)	21 mm				
scoring	1				

Labeler - Levins Pharmaceuticals, LLC (080839485)

 $\pmb{Registrant - \text{Levins Pharmaceuticals, LLC } (080839485)}$ 

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