

**TOBAKIENT- ascorbic acid, cholecalciferol, riboflavin, pyridoxine hcl, folic acid, l-glutathione, astaxanthin capsule**  
**Levins Pharmaceuticals, LLC**

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**Tobakient**

71905-0100-30

30 Capsules

**Tobakient™**

**Dietary Supplement**

Dispensed by Prescription



**DOSAGE AND ADMINISTRATION:** Usual adult dose is one (1) capsule once or twice daily or as prescribed by a licensed medical practitioner.

**KEEP OUT OF REACH OF CHILDREN**

**STORAGE AND HANDLING:** Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from heat, light, and moisture

Manufactured for:  
 Levins Pharmaceuticals, LLC  
 15121 Lemoyne Blvd  
 Biloxi, MS 39532



Rev. 01/19

3 71905 10030 1

**Supplement Facts**

Serving Size: 1 Capsule  
 Servings Per Container: 30

	Amount Per Serving	%DV
Vitamin C (as ascorbic acid)	200 mg	222%
Vitamin D3 (as cholecalciferol)	20 mcg	100%
Riboflavin (Vitamin B2)	1.7 mg	131%
Vitamin B6 (as Pyridoxine HCL)	2 mg	118%
Folic acid	1,667 mcg DFE	417%
	(1 mg folic acid)	
L-Glutathione (as Seteria®)(reduced)	250 mg	*
Astaxanthin (as AstaREAL®)		
(from Haematococcus pluvialis algae extract)	4 mg	*

\*Percent Daily Values (DV) Not Established

Other Ingredients: Microcrystalline Cellulose, Gelatin (from capsule), Magnesium Stearate, Silica, Titanium Dioxide, FD&C Blue 1

FOR PRODUCT INFORMATION PEEL HERE

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*Percent Daily Values (DV) Not Established		

Other Ingredients: Microcrystalline Cellulose, Gelatin (from capsule), Magnesium Stearate, Silica, Titanium Dioxide, FD&C Blue 1

Tobakient™ Capsules Dietary Supplement

## Health Claim

Dispensed by Prescription†

Tobakient™ is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients experiencing physiologically stressful conditions such as use of tobacco products, or to maintain levels when dietary intake of vitamins is inadequate or excretion or loss is excessive. ††

†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.

Tobakient™ 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.

Tobakient™ capsules are supplied as (blue and white, oblong-shaped) capsules in a child-resistant bottle of 30-count ("71905-0100-30").

\*\*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.

<b>TOBAKIENT</b>			
ascorbic acid, cholecalciferol, riboflavin, pyridoxine hcl, folic acid, l-glutathione, astaxanthin capsule			
<b>Product Information</b>			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:71905-100
Route of Administration	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)		RIBOFLAVIN	1.7 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)		ASCORBIC ACID	200 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)		PYRIDOXINE	2 mg
GLUTATHIONE (UNII: GAN16C9B8O) (GLUTATHIONE - UNII:GAN16C9B8O)		GLUTATHIONE	250 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)		CHOLECALCIFEROL	20 ug
ASTAXANTHIN (UNII: 8XPW32PR7I) (ASTAXANTHIN - UNII:8XPW32PR7I)		ASTAXANTHIN	4 mg

FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)		FOLIC ACID	1667 ug	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
GELATIN (UNII: 2G86QN327L)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:71905-100-30	30 in 1 BOTTLE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
dietary supplement		03/04/2019		

<b>Supplement Facts</b>	
<b>Serving Size :</b>	<b>Serving per Container :</b>
<b>Amount Per Serving</b>	<b>% Daily Value</b>
size (solid drugs)	21 mm
scoring	1
color	
color	
shape	

**Labeler** - Levins Pharmaceuticals, LLC (080839485)

**Registrant** - Levins Pharmaceuticals, LLC (080839485)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
FORMULIFE, INC.		024442806	