## PROVIDA OB- prenatal multivitamin mineral supplement enhanced with lactobacillus casei ke-99 capsule U.S. Pharmaceutical Corporation

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# Provida OB<sup>™</sup>

Serving Size: 1 Capsule			
		I	% Daily Value for Pregnant or
Amount Per Serving			Lactating Women
Vitamin C (as Sodium Ascorbate)	60 mg	67%	50%
Vitamin D <sub>3</sub> (Cholecalciferol)	10 mcg	50%	67%
Vitamin B <sub>1</sub> (as Thiamine Hydrochloride)	2.5 mg	208%	179%
Vitamin B <sub>2</sub> (Riboflavin)	3.5 mg	269%	219%
Vitamin B <sub>3</sub> (as Niacinamide)	10 mg	63%	56%
Vitamin B <sub>6</sub> (Pyridoxine HCl)	25 mg	1471%	1250%
Folic Acid	1.25 mg	313%	208%
Vitamin B <sub>12</sub> (Cyanocobalamin)	12 mcg	500%	429%
Biotin	300 mcg	1000%	857%
Pantothenic Acid (as Calcium d-Pantothenate)	6 mg	120%	86%
Iron (20 mg from Ferrous Fumarate; 20 mg from Polysaccharide Iron Complex)	40 mg	222%	148%
Magnesium (as Magnesium Oxide)	20 mg	5%	5%
Zinc (as Zinc Oxide)	10 mg	91%	77%
Copper (as Copper Gluconate)	1 mg	111%	77%
Lactobacillus casei KE-99 200 Billion CFU/g**	30 mg	†	+

\* % Daily Values are based on a 2,000 calorie intake of adults and children 12 years and older. † Daily value not established \*\*Colony-forming units (CFU) per gram at time of manufacturing

Other Ingredients: Titanium Dioxide, FD&C Blue #1, FD&C Red #40, Hypromellose, Magnesium Stearate and Microcrystalline Cellulose.

**INDICATIONS:** Provida OB<sup>™</sup> is a prenatal supplement designed to improve the nutritional status of women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Provida OB<sup>™</sup> may also be used to improve the nutritional status of women before conception.

**CONTRAINDICATIONS:** Provida OB<sup>™</sup> is contraindicated in patients with a known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. It is also contraindicated in patients suffering from pernicious anemia as folic acid may obscure its signs and symptoms.

**Ferrous Fumarate and Polysaccharide Iron Complex (PIC):** All Provida products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the formulation and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the lower gut, via an active protein transport mechanism".

*Clinical Studies: Picinni, L.-Ricciotti, M. 1982. Therapeutic effectiveness of an ironpolysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias: PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July-September 1982).* 

**Folic Acid:** Folic Acid is one of the important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

**WARNING:** Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin  $B_{12}$  is deficient.

**PRECAUTIONS:** Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure the signs and symptoms of pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive. The use of this product by

immunocompromised patients or treatment of any disorder must be medically supervised by a physician.

**OVERDOSE:** Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted.

**DOSAGE AND ADMINISTRATION:** Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

**HOW SUPPLIED:** Provida OB<sup>™</sup> are swedish orange opaque Vcaps<sup>®</sup> capsules printed in white "US" Logo on the cap and "ProV" on the body. Packed in child resistant cap and light resistant bottle of 30 capsules (52747-0504-30). The listed product number is not a National Drug Code. Instead, US Pharmaceutical Corporation has assigned this product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

## CAUTION: Rx only.

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.

## Prenatal Multivitamin & Mineral Supplement enhanced with Lactobacillus casei KE-99

Consult package literature for full prescription information. You should contact your healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036. Marketed by US Pharmaceutical Corporation. Manufactured with Vcaps® Plus capsule shells. Store at room temperature 15° to 30°C (59° to 86°F) and dry place. Manufactured in a FDA registered facility in the USA.

### Rev. 09/2022

Patent Numbers: USA: 6,797,266; 5,626,883; Mexico MX/a/2008/004461; Singapore: 200802623-9 and other countries. Vcaps<sup>®</sup> and the Vcaps<sup>®</sup> Logo are trademarks used under license.

## Packaging

52747-0504-30   30 Capsules   $R_X$ Only $Provida OB^{M}$		5	% Daily Value for Pregnant or actating Women	50%	67%	179%	219%	56%	1250%	208%	429%	857%	86%	148% Iron Complex)	5%	77%	77%	+	and children	), Hypromellose,	sre for Full iption ation
Prenatal Multivitamin & Mineral Supplement ← enhanced with Lactobacillus casei KE-99 Consult package literature for full prescriptio	roducts is a l st out of reac	0	% DV* Lac	67%	50%	208%	269%	63%	1471%	313%	200%	-	120%	40 mg 222% from Polysaccharide I	5%	91%	111%	÷	ike of adults ed manufacturir	Blue #1, FD&C Red #40,	Lift Here for Prescription Information
○ information. You should contact your healthcar provider for medical advice about adverse events To report a serious adverse event, contact US	se of iron-containing pro Ber 6. Keep this product call a doctor or poison			60 mg		_	3.5 mg	10 mg	25 mg	1.25 mg	12 mog	300 mog	6 mg	40 mg mg from Poly	20 mg	10 mg	1 mg	30 mg	00 calorie inta not establishe im at time of	&C Blue #1, F	
<ul> <li>Pharmaceutical Corporation, P.O. Box 360465</li> <li>Decatur, GA 30036. Marketed by U:</li> <li>Pharmaceutical Corporation. Manufactured wit</li> <li>Vcaps® Plus capsule shells. Store at roor</li> <li>temperature 15° to 30°C (59° to 86°F) and dry place</li> <li>Manufactured in a FDA registered facility in the USA</li> <li>CAUTION: Rx only. Rev. 09/2022</li> <li>Patent Numbers: USA: 6,797,266; 5,626,883; Mexic</li> <li>MX/a/2008/004461; Singapore: 200802623-9 and othe countries. Vcaps® and the Vcaps® Logo ar trademarks used under license.</li> </ul>	ING: Accidental overdo isoning in children un f accidental overdose,	Serving Size: 1 Capsule	Amount Per Serving	Vitamin C (as Sodium Ascorbate)	Vitamin D <sub>3</sub> (Cholecalciferol)	Vitamin B <sub>1</sub> (as Thiamine Hydrochloride)	Vitamin B <sub>2</sub> (Riboflavin)	Vitamin B <sub>3</sub> (as Niacinamide)	Vitamin B <sub>6</sub> (Pyridoxine HCI)	Folic Acid	Vitamin B <sub>12</sub> (Cyanocobalamin)	Blotin	Pantothenic Acid (as Calcium d-Pantothenate)	Iron (20 mg from Ferrous Fumarate; 20	Magnesium (as Magnesium Oxide)	Zinc (as Zinc Oxide)	Copper (as Copper Gluconate)	Lactobacillus casei KE-99 200 Billion CFU/g**	*% Daily Values are based on a 2,000 calorie intake of adults and children 12 years and older. † Daily value not established *Colony-forming undis (CFU) ber oram at time of manufacturing	Other Ingredients: Titanium Dioxide, FD&C	

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## Supplement Facts

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#### 52747-0504-30 Provida OB ™

B only

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Product Informa	ation						
Product Type		DIETARY SUPPLEMENT	ltem	Code (So	urce)	NHRIC:527	47-504
Route of Administration ORAL							
Active Ingredien	t/Active	Moiety					
-	Ing	redient Name			Basis of S	Strength	Streng
ASCORBIC ACID (UNII:	-	OR) (ASCORBIC ACID - U	NII:PQ6CK8PI	DOR)	ASCORBIC A	-	60 mg
	JNII: 1C6V7	7QF41) (CHOLECALCIFER	OL - UNII:1C6	5V77QF41)	CHOLECALCI	FEROL	400 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION -THIAMINE HYDROCHLORIDE2.5 mUNII: 4ABT0J945J)2.5 m							
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR) RIBOFLAVIN 3.5							
NIACIN (UNII: 2679MF6	87A) (NIACII	N - UNII:2679MF687A)			NIACIN		10 mg
PYRIDOXINE HYDROC UNII:KV2JZ1BI6Z)	HLORIDE	UNII: 68Y4CF58BV) (PYR	IDOXINE -		PYRIDOXINE		25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)FOLIC ACID							
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) CYANOCOBALAMIN							
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)         BIOTIN							
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID -       PANTOTHENIC ACID         UNII:19F5HK2737)       PANTOTHENIC ACID							
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)         IRON           MACHECHUM QXIDE (UNII: 2A2UQCIZIC) (MACHECHUM CATION - UNII:EEUU222)         MACHECHUM QXIDE							
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)MAGNESIUM OXIDEZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)ZINC CATION							
					ZINC CATION		10 mg
		23G6G67) (CUPRIC CATIC NII: SA940P2U00) (LACTIC		•	CUPRIC CATI LACTICASEIE CASEI		1 mg 30 mg
Inactive Ingredie	ents						
		Ingredient Nam	е			Str	ength
TITANIUM DIOXIDE (L	INII: 15FIX9	/2JP)					
FD&C RED NO. 40 (UI	NII: WZ B912	7XOA)					
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)							
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)							
MAGNESIUM STEARATE (UNII: 70097M6I30)							
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)							
Packaging							
# Item Code	Pack	age Description	Marketin	g Start D	ate Mar	keting E	nd Date
1 NHRIC:52747-504-30	30 in 1	BOTTLE					
INTRIC.32747-304-30							
I NHKIC.32747-304-30							
	format	ion					
Marketing Marketing Category		tion tion Number or Mor Citation	nograph		ing Start ate		ting End ate

Supplement	Facts	
Serving Size :		Serving per Container :
A	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	19 mm	
scoring	1	
imprint		

Labeler - U.S. Pharmaceutical Corporation (079467662)

Revised: 6/2023

U.S. Pharmaceutical Corporation