FEONYX- ascorbic acid, folic acid, methylcobalamin, ferrous fumarate, zinc citrate tablet, coated
Amella Pharma, LLC

FEONYX
Tablets with 150 mg Ferrous Fumarate

HEALTH CLAIM:
FEONYX Tablets Dietary Supplement with Iron

Dispensed by Prescription†

Supplements Facts Serving Size: 1 Tablet Servings per container: 28		
	Amount per Serving	**% Daily Value**
Vitamin C (as Ascorbic Acid)	60 mg	67%
Folate (1 mg Folic Acid)	1666 mcg DFE	417%
Vitamin B12 (as Methylcobalamin)	6 mcg	250%
Iron (as Ferrous Fumarate) (Equivalent to about 50mg of Elemental Iron)	150 mg	833%
Zinc (as Zinc Citrate)	15 mg	136%

OTHER INGREDIENTS: Cellulose, Docusate Sodium, Croscarmellose Sodium, Pharmaceutical Glaze, Calcium Stearate, Povidone, Silicon Dioxide

DESCRIPTION

FEONYX Tablets is a professionally prescribed orally administrated hematinic multivitamin/multimineral dietary supplement used to improve the nutritional status of patients with iron deficiency; this includes women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and non-lactating mothers. **THIS PRODUCT IS NOT INDICATED FOR USE IN CHILDREN.**

FEONYX Tablets are small, round, dark brown, clear-coated tablet, with debossed "A" on one side.

CONTRAINDICATIONS

FEONYX should not be used by patients with a known hypersensitivity to any of the listed ingredients. All iron compounds are contraindicated in patients with hemochromatosis, hemosiderosis, or hemolytic anemias.

PRECAUTIONS:

General: Take 2 hours after meals. Do not exceed recommended dose. Discontinue use if symptoms of intolerance appear. The type of anemia and the underlying cause or causes should be determined before starting therapy with FEONYX tablets. Ensure Hgb, Hct, Reticulocyte count are determined before

starting therapy and periodically thereafter during prolonged treatment. Periodically review therapy to determine if it needs to be continued without change or if a dose change is indicated. Since the anemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

Folic Acid: Folic acid alone is an improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia assessment, such that hematologic remission can occur while neurological manifestations remain progressive. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

Pediatric Use: Safety and effectiveness in pediatric population have not been established.

Geriatric Use: Safety and effectiveness in elderly population have not been established.

KEEP OUT OF REACH OF CHILDREN.

DRUG INTERACTIONS

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones

ADVERSE REACTIONS

Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parental administration of folic acid.

OVERDOSAGE

The clinical course of acute iron overdosage can be variable. Symptoms may include abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, hypotension, tachycardia, hyperglycemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.

WARNINGS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient.

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.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 tablet by mouth once daily or as directed by a physician. Do not chew tablet.

HOW SUPPLIED

FEONYX Tablets are small, round, dark brown, clear-coated tablet, with debossed "A" on one side.

FEONYX Tablets is available as the following:
72287-361-28* 28ct bottle

STORAGE

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from light, moisture and avoid excessive heat. Dispense in a tight, light resistant container as defined by the USP using a child-resistant closure.

Manufactured for:
Amella Pharma, LLC
E Brunswick, NJ 08816

Call your doctor for medical advice about side effects. You may report side effects to Amella Pharma, LLC at 1-844-385-0850.

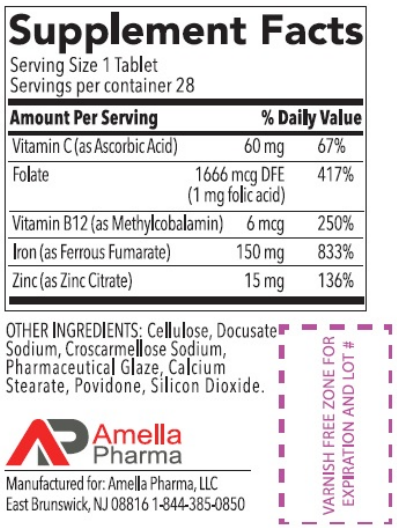
Issued: 06/2020 AP10102v1

*Amella Pharma 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.

† This product is a prescription-folate with or without other dietary ingredients that – due to increased folate 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)

Packaging



FEONYX

ascorbic acid, folic acid, methylcobalamin, ferrous fumarate, zinc citrate tablet, coated

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:72287-361

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	6 ug
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	150 mg
ZINC CITRATE (UNII: K72I3DEX9B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SHELLAC (UNII: 46N107B71O)	
CALCIUM STEARATE (UNII: 776XM7047L)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NHRIC:72287-361-28	28 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		11/18/2020	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	11 mm	
scoring	1	
imprint		

Labeler - Amella Pharma, LLC (081189492)