ASCORBIC ACID- ascorbic acid injection, solution
Raw Materials International Overseas LLC

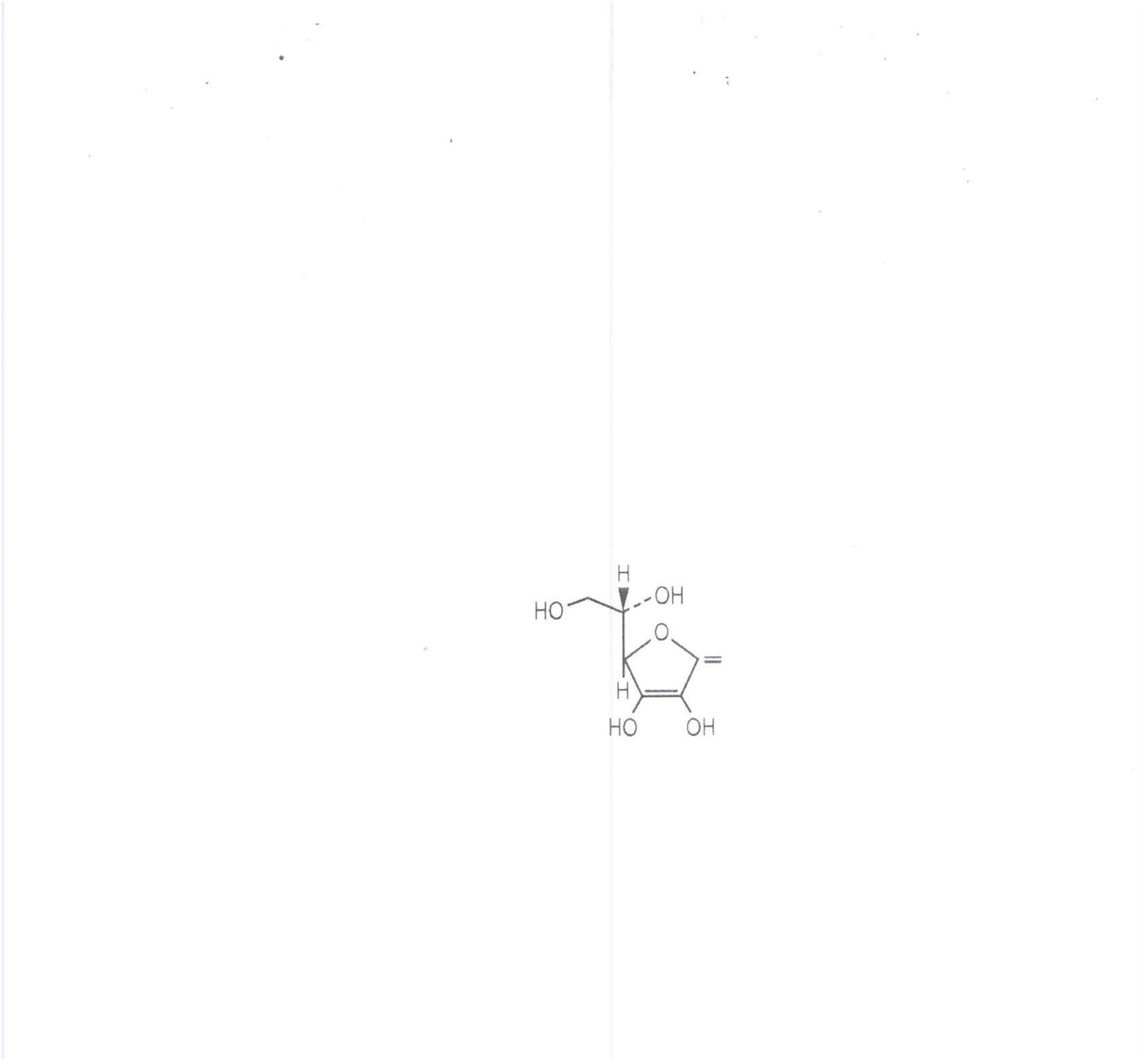
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Ascorbic box of 10 revised

FOR INTRAVENOUS, INTRAMUSCULAR OR SUBCUTANEOUS USE.
CONTAINS NO PRESERVATIVES.

Ascorbic Acid (vitamin C) is a water-soluble vitamin. It occurs as a white or slightly yellow crystal or powder with a light acidic taste. It is an antiscorbutic product. On exposure to air and light it gradually darkens. In the dry state it is reasonably stable in air, but in solution it rapidly oxidizes. Ascorbic Acid is freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, ether, and benzene.

The chemical name of Ascorbic Acid is L-ascorbic acid. The molecular formula is $C_6H_8O_6$ and the molecular weight is 176.13. The structural formula is as follows:



Ascorbic Acid injection is a clear, colorless to slightly yellow sterile solution of Ascorbic Acid in Water for Injection, for intravenous, intramuscular or subcutaneous use. Each mL contains: Ascorbic Acid 500 mg, Edetate Disodium 0.25 mg, Water for Injection q.s. pH (range 5.5-7.0) adjusted with Sodium Bicarbonate and Sodium Hydroxide. Contains no preservatives.

In humans, an exogenous source of ascorbic acid is required for collagen formulation and tissue repair. Ascorbic acid is reversibly oxidized to dehydroascorbic acid in the body. These two forms of the vitamin are believed to be important in oxidation-reduction reactions. The vitamin is involved in tyrosine metabolism, conversion of folic acid to folinic acid, carbohydrate metabolism, synthesis of lipids and proteins, iron metabolism, resistance to infections, and cellular respiration.

Ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency.

Ascorbic acid is recommended for the prevention and treatment of scurvy. Its parenteral administration is desirable for patients with an acute deficiency or for those whose absorption of orally ingested ascorbic acid is uncertain.

Symptoms of mild deficiency may include faulty bone and tooth development, gingivitis, bleeding gums, and loosened teeth. Febrile states, chronic illness, and infection (pneumonia, whooping cough, tuberculosis, diphtheria, sinusitis, rheumatic fever, etc.) increases the need for ascorbic acid. Hemovascular disorders, burns, delayed fracture and wound healing are indications for an increase in the daily intake.

There are no contraindications to the administration of ascorbic acid.

Diabetics, patients prone to renal calculi, those undergoing stool occult blood tests and those on sodium

restricted diets or anticoagulant therapy should not take excessive doses of ascorbic acid over an extended period of time.

General Precautions: Too-rapid intravenous injection is to be avoided.

Laboratory Tests: Diabetics taking more than 500 mg of ascorbic acid daily, may obtain false reading of the urinary glucose test. No exogenous ascorbic acid should be ingested for 48 to 72 hours before amine dependent stool occult blood tests are conducted because possible false negative results may occur.

Drug Interactions: Limited evidence suggests that ascorbic acid may influence the intensity and duration of action of bishydroxycoumarin.

Usage in Pregnancy: Pregnancy Category C

Animal reproduction studies have not been conducted with Ascorbic Acid Injection. It is also not known whether Ascorbic Acid Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ascorbic Acid Injection should be given to a pregnant woman only if clearly needed.

Nursing Mothers: Caution should be exercised when Ascorbic Acid Injection is administered to a nursing woman.

Transient mild soreness may occur at the site of intramuscular or subcutaneous injection. Too-rapid intravenous administration of the solution may cause temporary faintness or dizziness.

Ascorbic acid is usually administered orally. When oral administration is not feasible or when malabsorption is suspected, the drug may be administered intramuscularly, intravenously or subcutaneously. When given parenterally, utilization of the vitamin reportedly is best after IM administration, which is the preferred parenteral route.

For intravenous injection, dilution into a large volume parenteral such as Normal Saline or Glucose is recommended to minimize the adverse reactions associated with intravenous injection.

The average protective dose of ascorbic acid for adults is 70 to 150 mg daily. In the presence of scurvy, doses of 300 mg to 1 gram daily are recommended. However, as much as 6 grams have been administered parenterally to normal adults without evidence of toxicity.

To enhance wound-healing, doses of 300 to 500 mg daily for a week to ten days, both preoperatively and postoperatively, are generally considered adequate, although considerably larger amounts have been recommended. In the treatment of burns, doses are governed by the extent of tissue injury. For severe burns, daily doses of 1 to 2 grams are recommended. In other conditions in which the need for ascorbic acid is increased, three to five times the daily optimum allowances appear to be adequate.

PRESSURE MAY DEVELOP WITHIN THE VIAL UPON STORAGE.

Exercise care when withdrawing and/or relieve pressure by first inserting sterile empty syringe into vial thus allowing pressure to equilibrate.

When using dispensing vials use aseptic technique. Dispense entire contents in aliquots under a laminar flow hood without delay or within 4 hours after entry or discard remaining content after first withdrawal. Prepare stoppers with a suitable antiseptic solution. Do not use unless solution is clear and seal is intact.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

Ascorbic Acid for Injection, USP (500mg/mL)

NDC 69877-017-01

50mL Sterile Dispensing Vial, individually boxed, Rx only

NDC 69877-017-10

50 mL Sterile Dinspensing Vial, packaged in boxes of 10 vials, Rx only

PROTECT FROM LIGHT. STORE IN CARTON UNTIL TIMEOF USE: Store between 2° to 8°C (36° to 46°F).

Rev. 07/15

Manufactured for: **Raw Materials International Overseas LLC**, Miami, Florida, 33186

Ascorbic acid - Box 1 vial
Ascorbic acid - Box 10 vials
Ascorbic acid leaflet

PRECAUTIONS:

General Precautions: Too-rapid intravenous injection is to be avoided.

Laboratory Tests: Diabetics taking more than 500 mg of ascorbic acid daily, may obtain false reading of the urinary glucose test. No exogenous ascorbic acid should be ingested for 48 to 72 hours before amine dependent stool occult blood tests are conducted because possible false negative results may occur.

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Nursing Mothers: Caution should be exercised when Ascorbic Acid Injection is administered to a nursing woman.

ADVERSE REACTIONS:

Transient mild soreness may occur at the site of intramuscular or subcutaneous injection. Too-rapid intravenous administration of the solution may cause temporary faintness or dizziness.

DOSAGE AND ADMINISTRATION:

Ascorbic acid is usually administered orally. When oral administration is not feasible or when malabsorption is suspected, the drug may be administered intramuscularly, intravenously or subcutaneously. When given parenterally, utilization of the vitamin reportedly is best after IM administration, which is the preferred parenteral route.
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WARNING:

PRESSURE MAY DEVELOP WITHIN THE VIAL UPON STORAGE.
Exercise care when withdrawing and/or relieve pressure by first inserting sterile empty syringe into vial thus allowing pressure to equilibrate.
When using dispensing vials use aseptic technique. Dispense entire contents in aliquots under a laminar flow hood without delay or within 4 hours after entry or discard remaining content after first withdrawal. Prepare stoppers with a suitable antiseptic solution. Do not use unless solution is clear and seal is intact.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

HOW SUPPLIED:

Ascorbic Acid for Injection, USP (500 mg/mL)
NDC 69877-017-01
50 mL Sterile Dispensing Vial, packaged in boxes of 1 vial, RX only
NDC 69877-017-10
50 mL Sterile Dispensing Vial, packaged in boxes of 10 vials, RX only

PROTECT FROM LIGHT.
STORE IN CARTON UNTIL TIME OF USE:
Store between 2° to 8° C (36° to 46° F).

Rev. 07/15

Manufactured for:
Raw Materials International Overseas LLC
Miami FL 33186

RAW MATERIALS
International Overseas LLC

IDEAGRAFICA S.r.l.

PRODOTTO	CODICE PRODOTTO	FUSTELLA	TRACCIATO N°	DIMENSIONI	DIMENSIONI PIEG.	IMPIANTO DI PROPRIETA'
Ast. 10flc Ascorbic Acid 500mg/ml 50ml Raw	ZA415	1561	2777ZT	266x80x138		FISIOPHARMA

COLORI	COLORE 1	COLORE 2	COLORE 3	COLORE 4	COLORE 5	COLORE 6
5+V	CYAN	MAGENTA	GIALLO	NERO	P. 298	VERNICE OFFSET

BOZZA	DATA	IDG Nr.	OPERATORE	TESTO BRAILLE
6	07/02/17	17704	ROBERTO	

"SI PREGA DI LEGGERE ATTENTAMENTE LA PRESENTE BOZZA DI STAMPA.
NON CI ASSUMIAMO RESPONSABILITÁ SUCCESSIVAMENTE ALL'APPROVAZIONE DELLA STESSA DA PARTE DEL CLIENTE"

Rx only

Vial

LOT:

EXP:

For Intravenous, Intramuscular or Subcutaneous Use

500 mg/mL

Ascorbic Acid

Injection, USP

NDC 69877-017-10 50mL

10 x 50 mL

STORE BETWEEN 2° TO 8°C (36° TO 46°F).
Store in carton until time of use.
PROTECT FROM LIGHT.

PRESSURE MAY DEVELOP UPON STORAGE.
EXCERCISE CARE WHEN WITHDRAWING.

Manufactured for:

Raw Materials International Overseas LLC
Miami - FL 33186

Each mL contains: Ascorbic Acid 500 mg, Disodium Edetate 0.25 mg, in Water for Injection q.s.. pH (range 5.5 to 7.0) adjusted with Sodium Bicarbonate and Sodium Hydroxide.

Contains no preservatives.

USUAL ADULT DOSAGE: See package insert for full prescribing information.

WARNING: Use aseptic techniques. Dispense entire contents in aliquots under a laminar flow hood without delay or within 4 hours after entry,or discard remaining contents after first withdrawal. Prepare stoppers with a suitable antiseptic solution.

Do not use unless solution is clear and seal is intact.

REV: 07/15

RAW MATERIALS

Fust. 1561

ZA415

10 x 50 mL

Ascorbic Acid

Injection, USP

500 mg/mL

10 x 50 mL

NDC 69877-017-10 50mL

Ascorbic Acid

Injection, USP

500 mg/mL

RAW MATERIALS

For Intravenous, Intramuscular or Subcutaneous Use

Rx only

Vial

IDEAGRAFICA S.r.l.

IMPIANTO DI PROPRIETA': FISIOPHARMA

PRODOTTO	CODICE PRODOTTO	FUSTELLA	TRACCIATO N°	DIMENSIONI	DIMENSIONI PIEG.
Ast. 1flc Ascorbic Acid 500mg/ml 50ml Raw	ZA414	1535	1493ZT	85X50X50	

COLORI	COLORE 1	COLORE 2	COLORE 3	COLORE 4	COLORE 5	COLORE 6
5+V	CYAN	MAGENTA	GIALLO	NERO	P. 298	VERNICE OFFSET

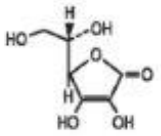
BOZZA	DATA	IDG Nr.	OPERATORE	TESTO BRAILLE
6	07/02/17	17703	ROBERTO	

"SI PREGA DI LEGGERE ATTENTAMENTE LA PRESENTE BOZZA DI STAMPA.
NON CI ASSUMIAMO RESPONSABILITÀ SUCCESSIVAMENTE ALL'APPROVAZIONE DELLA STESSA DA PARTE DEL CLIENTE"

ASCORBIC ACID INJECTION, USP
Rx Only
FOR INTRAVENOUS, INTRAMUSCULAR OR SUBCUTANEOUS USE.
CONTAINS NO PRESERVATIVES

DESCRIPTION:

Ascorbic Acid (vitamin C) is a water-soluble vitamin. It occurs as a white or slightly yellow crystal or powder with a light acidic taste. It is an antiscorbutic product. On exposure to air and light it gradually darkens. In the dry state it is reasonably stable in air, but in solution it rapidly oxidizes. Ascorbic Acid is freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, ether, and benzene.
The chemical name of Ascorbic Acid is L-ascorbic acid. The molecular formula is $C_6H_8O_6$ and the molecular weight is 176.13. The structural formula is as follows:



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CLINICAL PHARMACOLOGY:

In humans, an exogenous source of ascorbic acid is required for collagen formulation and tissue repair. Ascorbic acid is reversibly oxidized to dehydroascorbic acid in the body. These two forms of the vitamin are believed to be important in oxidation-reduction reactions. The vitamin is involved in tyrosine metabolism, conversion of folic acid to folinic acid, carbohydrate metabolism, synthesis of lipids and proteins, iron metabolism, resistance to infections, and cellular respiration.
Ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency.

INDICATIONS AND USAGE:

Ascorbic acid is recommended for the prevention and treatment of scurvy. Its parenteral administration is desirable for patients with an acute deficiency or for those whose absorption of orally ingested ascorbic acid is uncertain.
Symptoms of mild deficiency may include faulty bone and tooth development, gingivitis, bleeding gums, and loosened teeth. Febril states, chronic illness, and infection (pneumonia, whooping cough, tuberculosis, diphtheria, sinusitis, rheumatic fever, etc.) increases the need for ascorbic acid. Hemrovascular disorders, burns, delayed fracture and wound healing are indications for an increase in the daily intake.

CONTRAINDICATIONS:

There are no contraindications to the administration of ascorbic acid.

WARNINGS:

Diabetics, patients prone to recurrent renal calculi, those undergoing stool occult blood tests and those on sodium restricted diets or anticoagulant therapy should not take excessive doses of ascorbic acid over an extended period of time.

ASCORBIC ACID

ascorbic acid injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69877-017
Route of Administration	SUBCUTANEOUS, INTRAVENOUS, INTRAMUSCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	500 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.25 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69877-017-01	1 in 1 BOX	02/12/2017	
1		50 mL in 1 VIAL, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/02/2015	

Labeler - Raw Materials International Overseas LLC (079829477)

Revised: 2/2017 Raw Materials International Overseas LLC