

Summary of Product Characteristics



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المكتب العلمي:

مدخل ٥ - المبنى التجارى الثانى

المنطقة الخامسة, مساكن

الشيراتون رقم بريدى ١١٣٦١

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مكتب الاسكندرية:

عمارات ضباط مصطفى كامل

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تليفون: +٢٠٣٥٤٥٧١٤٠

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فاكس: +٢٠٣٥٤٥٧١٤٠

1. Name Of The Medicinal Product:

Immu - C Effervescent Sachet

2. Qualitative and Quantitative Composition:

Each Sachet (5 gm) contains:		
Active ingredient:		
Echinacea Dry Ext. (4:1)	200 mg	USP35
Vit. C	500 mg	B.P 2015
Zinc Sulphate monohydrate	38.4 mg	U.S.P 35
Inactive ingredient:		
Citric acid	0.56 gm	B.P 2015
Sodium bicarbonate	0.70 gm	B.P 2015
Povidone K 25	20 mg	B.P 2015
Saccharin sodium	21 mg	B.P 2015
Lactose monohydrate	2.960 gm	B.P 2015

3. Pharmaceutical Form:

Effervescent Sachet

4. Clinical Particulars:

4.1 Therapeutic Indications:

- 1- For prevention and treatment of common cold and influenza.
2. Acute and chronic upper respiratory tract infections.
3. Chronic or subacute rhinitis.
4. Chronic sinusitis.
5. Subacute tonsillitis.

4.2 Posology And Method Of Administration:

For most patients, the recommended dose is one sachet twice daily.
Add content of one sachet to half glass of water to be taken while effervescing.

4.3 Contraindications:

Immu-C is contraindicated in daisy Allergy.

- Do not use Immu-C if pregnant or breast feeding because ingestion of large doses of Vitamin C during pregnancy has resulted in scurvy in neonates.



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محمول: ٠١٢٢٧٦٩٣ ٣٣٦

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أبو سلطان - فayed

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٠١٢٢٧١٩٣٣٨٨

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مكتب الاسكندرية:

عمارات ضباط مصطفى كامل

عمارة ٢١ شقة ٣٣

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فاكس: ٠٣٥٤٥٧١٤٠

- Immu-C Effervescent Sachets is contraindicated in progressive autoimmune or systemic disease due to its Echinacea contents:

1. Acquired Immune Deficiency (AIDS).
2. Tuberculosis.
3. Rheumatoid Arthritis.
4. Systemic Lupus Erythematosus (SLE).
5. Multiple Sclerosis.
6. Acute Asthma Attack.
7. Allergic Rhinitis.

• **4.4 Special Warnings And Precautions For Use:**

-Taking Immu-C with food may decrease stomach upset.

- Avoid taking Immu-C with foods high in calcium or phosphorus. These foods may decrease the absorption of zinc.

4.5 Interaction with Other Medicinal Products and Other Forms Of Interaction:

If used Immu-C, tell your doctor of all prescription and nonprescription medication you may use, especially of: "blood thinners" (e.g., warfarin), drugs that affect the immune system (e.g., cyclosporine, prednisone).

- If used beyond 8 weeks, Echinacea could cause hepatotoxicity and therefore should not be used with other known hepatotoxic drugs, S.C. as anabolic steroids, amiodarone, methotrexate, and ketoconazole.

- Concurrent administration of more than 200 mg of ascorbic acid per 30 mg of elemental iron increases absorption of iron from the GI tract; however, most individuals are able to absorb orally ingested iron adequately without concurrent administration of ascorbic acid.

-Increased urinary excretion of ascorbic acid and decreased excretion of aspirin occur when the drugs are administered concurrently. Salicylates inhibit uptake of ascorbic acid by leukocytes and platelets. As a result, leukocyte and plasma concentrations of ascorbic acid are decreased to concentrations slightly higher than those associated with tissue depletion of the vitamin; however, there is no evidence to date that salicylate therapy precipitates ascorbic acid deficiency. Although concomitant administration of ascorbic acid supplements in patients receiving salicylates increases plasma ascorbic acid concentrations, leukocyte ascorbic acid concentrations are not increased and tissue stores of the vitamin may not be increased. Therefore, routine administration of ascorbic acid supplements to patients receiving salicylates is not warranted; however, patients receiving high dosages of salicylates who exhibit any signs or symptoms of ascorbic acid deficiency should be evaluated for such a deficiency. Concurrent administration of ascorbic acid and fluphenazine reportedly resulted in decreased fluphenazine plasma concentration.

- Acidification of the urine following administration of ascorbic acid may result in altered excretion of other drugs.



• 4.6 Pregnancy And Lactation

- No documented adverse effects associated with Immu-C therapy during pregnancy apparently exist, but neither have adequate, well-controlled studies been performed.
- Zinc passes into breast milk. While there have been no reports of harm to nursing infants

Do not use Immu-C if pregnant or breast feeding because ingestion of large doses of Vitamin C during pregnancy has resulted in scurvy in neonates.

4.7 Effects on Ability to Drive and Use Machines:

Not applicable

• 4.8 Undesirable Effects:

It is expected that people using Immu-C do not have serious side effects.

Rarely, Immu-C Effervescent Sachets may cause GI side effects such as upset stomach, unpleasant taste, nausea, vomiting, dyspepsia, diarrhea, heartburn, abdominal cramps, mouth sores.

In the unlikely event an allergic reaction to Immu-C Effervescent Sachets may occur, symptoms of an allergic reaction include: rash, itching, difficulty breathing; closing of the throat; swelling of the lips, tongue, or face; or hives & dizziness.

Immunosuppression may occur with prolonged use of Immu-C Effervescent Sachets due to its Echinacea contents:

- Opportunistic infections
- Impaired wound healing

- Hepatotoxicity risk with prolonged use of Immu-C® Effervescent Sachets due to its Echinacea contents.

- Immu-C Effervescent Sachets may cause ocular side effects & photosensitivity due to its Echinacea contents.

-Immu-C Effervescent Sachets may cause (Rare due to its Vitamin C contents)

-Frequent urination

- Kidney stones may develop, its symptoms are: abdominal/back pain, painful urination.

Urinary calcium may increase, and urinary sodium may decrease after 3–6 g of ascorbic acid daily. Ascorbic acid reportedly may affect glycogenolysis and may be diabetogenic; however, this is controversial.

- Other adverse effects reportedly associated with high vitamin C intake include diminished high-altitude tolerance, erythema, flushing, fatigue, headache and erosion of dental enamel.

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مكتب الاسكندرية:

عمارات ضباط مصطفى كامل

عمارة ٢١ شقة ٣٣

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محمول: ٢٠١٢٢٧١٩٣٣٩٩

فاكس: ٢٠٣٥٤٥٧١٤٠

Patients with glucose-6-phosphate dehydrogenase deficiency reportedly have developed hemolysis after large oral doses of ascorbic acid. Rarely, decreased blood pH leading to sickle-cell crisis has been reported in patients with sickle cell disease.

Serum cholesterol concentrations reportedly decreased in healthy individuals younger than 25 years of age and increased in atherosclerotic patients after administration of 1g of ascorbic acid daily; however, these reports have been disputed. Doses of 600 mg or greater of ascorbic acid have been reported to have a diuretic action.

Zinc may cause these unlikely but serious side effects: Fever, chills, sore throat, and sores in mouth, unusual tiredness, and weakness.

• 4.9 Overdose:

It is expected that Immu-C Effervescent Sachets is safe in high doses as no cases of Echinacea over dosages in humans has been reported:

- 1) Echinacea contains pyrrolizidine alkaloids it is not considered to be hepatotoxic, as they do not contain the 1, 2-unsaturated necine ring which has been linked with liver damage.
- 2) Single oral doses of the expressed juice of Echinacea purpurea (EP) proved virtually non-toxic to rats and mice. After 4 weeks of oral administration in doses amounting to many times the human therapeutic dose laboratory tests and necropsy findings gave no evidence of any toxic effects in rats.
 - Symptoms of Immu-C Effervescent Sachets overdose may include, change amount of urine or joint pain due to its vitamin C contents.
 - Symptoms of of Immu-C Effervescent Sachets overdose may include, chest pain, vomiting, yellowish tinge to eyes or skin, dehydration, shortness of breath, restlessness, profuse sweating, dizziness due to its zinc contents.
 - Consumption of more than 100mg of zinc supplement per day may increase the risk of prostate cancer.

• 5. Pharmacological Properties:

Echinacea has been attributed with several pharmacological effects such as: influencing pro-inflammatory enzymes, stimulating proliferation and activity of polymorph nuclear cells, protecting cells against free-radical damage, activating monocytes to produce cytokines, and possibly by weakly stimulating humeral immunity. All these effects culminate in improved protection against systemic, infectious diseases. Ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, and lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency.



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مكتب الاسكندرية:

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• **5-1 Pharmacokinetic Properties:**
Absorption:

Ascorbic acid is readily absorbed after oral administration; however, absorption involves an active process and may be limited after very large doses. With usual dietary intake of ascorbic acid (30–180 mg daily), about 70–90% of the amount of vitamin ingested is absorbed. At dosages exceeding 1 g daily, absorption decreases to about 50% or less. In one study in healthy individuals, only 50% of a single 1.5-g oral dose of ascorbic acid was absorbed. GI absorption of ascorbic acid may be reduced in patients with diarrhea or GI diseases.

Normal plasma concentrations of ascorbic acid are about 10–20 mcg/mL; plasma concentrations below 1–1.5 mcg/mL are associated with scurvy. Total body stores of ascorbic acid have been estimated to be about 1.5 g with about a 30–45 mg daily turnover. 20% to 30% of dietary Zinc is absorbed from the GI tract, peak plasma concentration occurs in approximately 2 hours.

Distribution:

Ascorbic acid is widely distributed in body tissues. Large concentrations of the vitamin are found in the liver, leukocytes, platelets, glandular tissues, and the lens of the eye. About 25% of the ascorbic acid in plasma is bound to proteins.

Ascorbic acid crosses the placenta; cord blood concentration are generally 2–4 times the concentration in maternal blood. Ascorbic acid is distributed into milk. Milk of nursing mothers on a normal diet contains 40–70 mcg of the vitamin / mL.

Over 85 percent of total body zinc is incorporated into skeletal muscle and bone. Plasma zinc, bound primarily to albumin at a concentration of approximately 10-15 umol/L, represents only 0.1% of total body levels, 30-40 % to alpha 2 macroglobulins or transferrin and 1% to amino acids like histidine and cysteine.

Elimination:

Ascorbic acid is reversibly oxidized to dehydroascorbic acid. Some ascorbic acid is metabolized to inactive compounds including ascorbic acid-2-sulfate and oxalic acid which are excreted in the urine. There is a renal threshold for ascorbic acid of approximately 14 mcg/mL; however, the threshold varies among individuals. When the body is saturated with ascorbic acid and blood concentrations exceed the threshold, unchanged ascorbic acid is excreted in the urine. When tissue saturation and blood concentrations of ascorbic acid are low, administration of the vitamin results in little or no urinary excretion of ascorbic acid. Ascorbic acid is removed by hemodialysis.

The main excretion route of dietary Zinc is through the intestine. Only minor amounts are lost in urine (~2%).

Zinc loss from the body also is attributable to epithelial cell desquamation, Sweat, semen, hair, and the menstrual cycle.

Endogenous Zinc be reabsorbed in ileum and colon creating enterohepatic circulation of Zinc.



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6. Pharmaceutical Particulars:

6.1 List Of Excipients:

Citric acid	0.56 gm
Sodium bicarbonate	0.70 gm
Povidone K 25	20 mg
Saccharin sodium	21 mg
Lactose monohydrate	2.960 gm

6.2 Incompatibilities:

- All excipients comply with their BP Pharmacopoeia monograph.
- None of the excipients contains materials of animal or human origin.
- No genetically modified organisms (GMO) have been used in the preparation of these products.
- No incompatibilities with the excipients or packaging materials have been shown during research of pre-formulation and formulation studies and nor during manufacturing processing and stability.

6.3 Shelf Life

3 years

6.4 Special Precautions For Storage:

No special precaution for storage

Store in a dry place at temperature not exceeding 30° C.

6.5 Nature And Contents Of Container:

Carton box containing 10 sachets of 4 layers (paper, extruded LDPE, aluminum foil, extruded LDPE with inner insert

6.6 Special Precautions For Disposal And Other Handling:

Keep out of reach of children

7. Marketing Authorization Holder:

Arab Company for Pharmaceuticals & Medicinal Plants (Mepaco – Medi food) Egypt

8. Marketing Authorization Number(S)

Reg. No: 584/2004

Reg. No: 27/2017

9. Date Of First Authorization/Renewal Of The Authorization:

Reg. No: 584/2004

Authorization date: 17/02/2004

Reg. No: 27/2017

Authorization date: 30/03/2017

R&D Manager

Dr. / Mohamed Eldegwy



www.mepaco-pharma.net

Operating Under Law 43 Issued 1974 – Commercial Register No. 866 – Capital 400 EGP Million

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خاضعة لأحكام قانون ٤٣ لسنة ١٩٧٤ وتعديلاته سجل رقم ٨٦٦ استثمار رأس المال المرخص به ٤٠٠ مليون جنيه مصري



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الشيراتون رقم بردي ١١٣٦١

هليوبوليس - الحربة

تليفون: ٠٢٠٢٢٦٧٣١٧٥

٠٢٠٢٢٦٧٣١٧٦

محمول: ٠٢٠١٢٢٧١٩٣٣٧٧

٠٢٠١٢٢٧١٩٣٣٨٨

فاكس: ٠٢٠٢٢٦٧٤٩٣٤

مكتب الإسكندرية:

عمارات ضباط مصطفي كامل

عمارة ٢١ شقة ٣٣

تليفون: ٠٢٠٣٥٤٥٧١٤٠

محمول: ٠٢٠١٢٢٧١٩٣٣٩٩

فاكس: ٠٢٠٣٥٤٥٧١٤٠