

## What is in this leaflet

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## What *Lussi* is used for

Ascorbic acid + Zinc (*Lussi*) effervescent tablets are indicated for the treatment of vitamin C and zinc deficiency.

## How *Lussi* works

**Vitamin C:** Ascorbic acid is an important water-soluble vitamin and antioxidant. Due to the low storage capacity of the body for vitamin C, a regular intake of sufficient amounts is essential to humans.

Ascorbic acid and its metabolite dehydroascorbic acid form a reversible redox system that is involved in many enzymatic reactions and forms the basis for the spectrum of action of vitamin C. Ascorbic acid functions as a cofactor in a number of hydroxylation and amidation reactions by transferring electrons to enzymes that provide reducing equivalents.

The importance of ascorbic acid to the human body is most clearly evident in clinically manifest vitamin C deficiency, i.e. scurvy. Ascorbic acid plays a key role in the production of hydroxyproline from proline, which in turn is essential to the development of functionally active collagen. The symptoms seen in scurvy, such as delayed wound healing, disturbances of bone growth, vascular fragility, and disorders of dentine formation, are the result of impaired collagen formation.

**Zinc:** As with vitamin C, low levels of zinc may also adversely affect the healing rate of wounds, ulcers and decubitus.

Zinc status is of major importance in maintenance of effective immune response, particularly T-cell-mediated response.

## Before you use *Lussi*

### - When you must not use it

Patients suffering from renal insufficiency should consult a physician or healthcare professional prior to intake of large doses of ascorbic acid.

Do not exceed the recommended doses. Acute or chronic overdose (> 2 g/day) increases risk of adverse effects including formation of calcium oxalate deposits, acute tubular necrosis, and/or renal failure.

Patients suffering from glucose-6-phosphatase deficiency should not take higher than the recommended dose. Overdose of vitamin C in this patient population has been associated with hemolytic anemia.

Patients receiving other single vitamins or multivitamin preparations, any other medication or those under medical care must consult a health care professional before taking this product.

Separate the intake of the product from other medication by 4 hours unless otherwise specified.

Vitamin C may interfere with laboratory tests resulting in false readings. Inform your physician when taking this product and diagnostic measures are planned or done.

Vitamin C may interfere with test kits and meters measuring glucose levels resulting in false results. Please check the package insert of the test kit or meter for guidance.

*Lussi* Effervescent contains a source of phenylalanine. Therefore, may be harmful to people with phenylketonuria. This medicinal product contains 194 mg sodium per tablet, equivalent to 9.7% of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult. This should be taken into consideration by patients on a controlled sodium diet.

## ***Pregnancy and lactation***

The product is generally considered safe during pregnancy and lactation when used as labelled. However, since there are no sufficient controlled human studies assessing the risk of the product during pregnancy or lactation, the product should be administered in pregnancy or lactation only when

clinically indicated and considered essential by the physician.

The labelled dose should not be exceeded as chronic overdose might be harmful to the foetus and neonate.

Vitamin C and Zinc are secreted into breast milk. This must be taken into consideration if the infant is receiving any other supplements.

Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

## ***Fertility***

To date, there is no evidence suggestive that vitamin C and/or zinc causes adverse reproductive effects in humans.

## **How to use *Lussi***

### *Dosage*

Adults and children over 12 years: 1 effervescent tablet a day dissolved in a glass of water (200 ml).

*Mode of administration:* Oral

### - If you use too much (overdose)

There is no evidence that this product can lead to an overdose when used as recommended.

Allowance should be made for intake of vitamin C and zinc from all other sources.

Clinical signs and symptoms, laboratory findings, and consequences of overdose are highly diverse, dependent on an individual's susceptibility and surrounding circumstances.

General manifestations of overdose with vitamin C and/or zinc may include increase of gastrointestinal disturbances including diarrhea, nausea, and vomiting.

If such symptoms occur, the product should be stopped and a healthcare professional consulted.

Specific clinical manifestations may include the following:

***Vitamin C:*** Acute or chronic overdose of vitamin C may significantly elevate serum and urinary oxalate levels. In

some instances, this may lead to hyperoxaluria, calcium oxalate crystalluria, calcium oxalate deposition, kidney stone formation, tubulointerstitial nephropathy, and acute renal failure. Individuals with mild to moderate renal insufficiency may be susceptible to these effects of vitamin C toxicity at lower doses and should consult a health care professional before use of the product.

Overdose of vitamin C may result in oxidative hemolysis or disseminated intravascular coagulation in patients with glucose-6-phosphate dehydrogenase deficiency.

**Zinc:** Zinc overdose can cause irritation and corrosion of the gastrointestinal (GI) tract, acute renal tubular necrosis, interstitial nephritis, copper deficiency, sideroblastic anemia, and myeloneuropathies.

If overdose with the product is suspected, intake should be stopped and a health care professional consulted for treatment of clinical manifestations. Vitamin C is removed by hemodialysis.

#### **While you are using it**

##### **- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Lussi*.

##### **- Things you must not do**

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

*Lussi* Effervescent is contraindicated in;

-Hypersensitivity to any of the active substances or to any of the excipients listed in section 6. 1.

-Patients suffering from or having a history of Nephrolithiasis must not take this product.

-Patients suffering from oxalate urolithiasis or oxaluria must not take this product.

-Patients suffering from severe renal insufficiency or renal failure must not

take the product. This includes patients on dialysis.

-Patients suffering from Hemochromatosis must not take this product.

##### **- Things to be careful of** **Driving and using machines**

The product has no or negligible influence on the ability to drive and use machines.

#### **Undesirable effects**

The listed adverse drug reactions have been identified during the post-approval use of the product. As these reactions are reported voluntarily, a reliable estimation of their frequency is not possible.

***Gastrointestinal disorders:*** Diarrhoea, nausea, vomiting, gastrointestinal and abdominal pain.

***Immune system disorders:*** Allergic reaction, anaphylactic reaction, anaphylactic shock.

Hypersensitivity reactions with respective laboratory and clinical manifestations include allergic asthma syndrome, mild to moderate reactions potentially affecting skin, respiratory tract, gastrointestinal tract and cardiovascular system, including symptoms such as rash, urticaria, allergic edema and angioedema, pruritus, cardiorespiratory distress, and, severe reactions, including anaphylactic shock have been reported.

#### **Storage and Disposal of *Lussi***

##### **- Storage**

Store at temperatures below 30°C.

##### **- Disposal**

No special requirements.

#### **Product Description**

##### **- What it looks like**

Light orange to orange color, round shape mottled tablets plain on both sides.

##### **- Ingredients**

Active ingredient: Vitamin C (L-Ascorbic acid) and Zinc Citrate Trihydrate equivalent to Zinc

Inactive ingredients: Sorbitol, sodium bicarbonate, anhydrous sodium carbonate, aspartame, acesulfame

potassium, sodium chloride, IF1212 orange flavor SD, color annatto, polyethylene glycol 6000.

#### **Manufacturer**

##### **Kusum Healthcare Private Limited**

Plot No. M-3, Indore Special Economic Zone,  
Phase-II, Pithampur, Distt. Dhar,  
Madhya Pradesh, India.

#### **Product Registration Holder**

##### **Kusum Healthcare Pvt. Ltd.**

#### **Date of revision**

04/2022