

ESCAVITE® LQ

LIQUID MULTI-VITAMIN SUPPLEMENT WITH IRON AND FLUORIDE 0.25 mg

Rx Only

Nutrition Facts

Serving size: 1.0 mL (Mark on Dropper)

Amount Per Table	Infants	% Daily Value Children Age under 4 Years
Vitamin A	1,500 IU	100%
Vitamin C	35 mg	100%
Vitamin D	400 IU	100%
Vitamin E	7.5 IU	150%
Thiamine	0.5 mg	100%
Riboflavin	0.6 mg	100%
Niacin	8 mg	100%
Vitamin B6	0.4 mg	100%
Vitamin B12	0.9 mcg	45%
Iron	6 mg	40%
Fluoride	0.25 mg	60%

*Daily Value not established for patients who are in need of supplementation as directed by a licensed medical practitioner.

Active ingredient for caries prophylaxis:

Each 1 mL contains 0.25 mg fluoride as sodium fluoride.

Other ingredients: Ascorbic Acid (Vitamin C), Carrageenan, Cholecalciferol (Vitamin D3), Citric Acid, Cyanocobalamin (Vitamin B12), D-alpha-tocopheryl acetate (Vitamin E), Ferrous Glycine Cysteinate, Ferric Pyrophosphate, Glycerin, Niacin, Orange Flavor, Polysorbate 80, Potassium Sorbate, Propylene Glycol, Purified Water, Pyridoxine Hydrochloride (Vitamin B6), Riboflavin (Vitamin B2), Thiamin Hydrochloride (Vitamin B1), Vitamin A Palmitate, and Sucralose.

Professional labeling

CLINICAL PHARMACOLOGY:

It is well established that fluoridation of the water supply (1ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries. Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the hydroxyapatite in the tooth as it is formed to produce the more caries-resistant crystal, fluorapatite. Three stages of fluoride deposition in tooth enamel can be distinguished:¹

- 1) Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
- 2) After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
- 3) After eruption, the surface enamel acquires fluoride from water, food, supplementary fluoride, and smaller amounts from saliva.

INDICATIONS AND USAGE:

Supplementation of the diet with nine essential vitamins and iron, and supplementation of the diet with fluoride for caries prophylaxis.

The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.²

Escavite LQ Multi-vitamin with Iron and Fluoride 0.25 mg provides fluoride in drop form for infants and young children from 6 months to 3 years of age in areas where the drinking water contains less than 0.3 ppm of fluoride and for children ages 3-6 years in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride.^{2,3}

Each 1.0 mL supplies sodium fluoride (0.25 mg fluoride per 1 mL) plus nine essential vitamins and iron.

Escavite LQ Multi-vitamin with Iron and Fluoride 0.25 mg supplies significant amounts of vitamins A,C,D,E, thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and iron to supplement the diet, and to help assure the deficiencies of these nutrients will not develop. Thus, in a single easy-to-use preparation, infants and children obtain nine essential vitamins and iron, plus fluoride.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

WARNINGS: As in the case of all medications, keep out of reach of children.

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

PRECAUTIONS:

The suggested dose should not be exceeded since dental fluorosis may result from continued ingestion of large amounts of fluoride.

When prescribing Escavite LQ Multi-vitamin with Iron and Fluoride 0.25 mg drops:

- 1) Determine the fluoride content of the drinking water from all major sources.
- 2) Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.
- 3) Periodically check to make sure that the child does not develop significant dental fluorosis.

Escavite LQ Multi-vitamin with Iron and Fluoride 0.25 mg drops should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation. (The amount of sodium fluoride in the 50-mL size is well below the maximum to be dispensed at one time according to recommendations of the American Dental Association.)

Drug Interactions: Do not eat or drink dairy products within one hour of fluoride administration. Incompatibility of fluoride with dairy foods has been reported due to formation of calcium fluoride which is poorly absorbed.

ADVERSE REACTIONS:

Allergic rash and other idiosyncrasies have been rarely reported. To report adverse side effects or to obtain product information, contact GM Pharmaceuticals, Inc. at 1-888-535-0305.

DOSAGE AND ADMINISTRATION:

1 mL daily, or as prescribed. Includes easy to use dropper. To administer directly, place the dropper directly inside child's mouth with the tip against the inside of the cheek. A firm pressure on the dropper bulb will deliver the proper dose. A slight excess will remain in the dropper. If preferred the drops may be slowly mixed with formula, juice, cereal or other food and fed within 1 hour.

HOW SUPPLIED:

Escavite LQ Multi-vitamin with Iron and Fluoride 0.25 mg drops is an orange to dark orange liquid with an orange odor available in 50 mL bottles with accompanying calibrated dropper. (Product Code: 58809-877-50)

STORAGE:

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

See USP Controlled Room Temperature. Protect from light and moisture.

Close tightly after each use.

Shake Well. Use calibrated dropper.

KEEP OUT OF REACH OF CHILDREN.

Occasional deepening of color has no significant effect on vitamin potency.

While taking drops with iron, a slight darkening of the teeth may occur. Brushing will minimize this temporary condition. After opening, store away from direct light. Your doctor or dentist is the best source of counsel and guidance in your child's fluoride supplementation.

REFERENCES:

1. Brudevold F, McCann HG. Fluoride and caries control - Mechanism of action. In: Nizel AE, ed. The Science of Nutrition and Its Application in Clinical Dentistry. Philadelphia: WB Saunders Co.; 1966:331-347.
2. American Academy of Pediatrics, Committee on Nutrition: Fluoride Supplementation for Children: Interim Policy Recommendations. AAP News, February 1995, pg 18.
3. American Dental Association Council on Dental Therapeutics. New Fluoride Schedule Adopted. ADA News. May 16, 1994;12-14.

Manufactured for: GM Pharmaceuticals, Inc., Arlington, TX 76015
Covered by U.S. Patent No. 7,341,708.