



MyKidz IronFL™

For Infants and Toddlers

Liquid Iron Suspension with Vitamins A, C, & D and Fluoride Rx Only

WARNING

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

Nutrition Facts Serving Size 2 mL Daily		
Amount Per 2 mL	% Daily Value	
	Infants	Children Under Age 4 Years
Vitamin A 1500 IU	100%	60%
Vitamin C 35 mg	100%	88%
Vitamin D 400 IU	100%	100%
Iron 10 mg†	67%	100%
Fluoride 0.25 mg	*	*

† Amount of Elemental Iron

* % Daily Value not established.

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride. **Other ingredients:** Ascorbic acid, butylated hydroxyanisole, cholecalciferol, ferrous sulfate, glycerin, high fructose corn syrup, methylparaben, modified starch, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, sodium polystyrene sulfonate, strawberry banana flavor, sucralose, vitamin A palmitate, and xanthan gum.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm 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*. The reaction may be expressed by the equation¹:



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

MyKidz Iron FL™ may be useful for infants whose diets are lacking in vitamins A, C, D, and iron.

MyKidz Iron FL™ also provides fluoride for caries prophylaxis.

MyKidz Iron FL™ was developed to provide fluoride in liquid 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 to 6 years in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride.^{2,3} Each 2.0 mL supplies sodium fluoride (0.25 mg fluoride) plus three basic vitamins and iron.

PRECAUTIONS

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

When prescribing MyKidz Iron FL™:

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.

MyKidz Iron FL™ should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation. (The amount of sodium fluoride in the 118 mL size is well below the maximum to be dispensed at one time according to recommendations of the American Dental Association).

Your doctor or dentist is the best source of counsel and guidance in your child's fluoride supplementation.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

To report SUSPECTED ADVERSE REACTIONS, contact Tris Pharma, Inc. (1-732-940-0358) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

2.0 mL daily, or as prescribed. Dispense directly into child's mouth with the oral dispenser. USE FULL DOSAGE.

HOW SUPPLIED

MyKidz Iron FL™ is available in bottles of 4 fl. oz. (118 mL) with accompanying adapter and an oral dispenser with stand, and as physician samples in bottles of 1 fl. oz. (29.5 mL).

NDC 27808-004-04 Bottles of 4 fl. oz. (118 mL)

NDC 27808-004-01 Bottles of 1 fl. oz. (29.5 mL) Physician Sample

Store at room temperature, 59° to 86°F (15° to 30°C). For more information visit www.mykidziron.com

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. *Pediatrics*. 1995;95(5):777.
3. American Dental Association Council on Dental Therapeutics. New Fluoride Schedule Adopted. *ADA News*. May 16, 1994;12-14.

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