



Ingestible fluoride drug products: What health care professionals should know

October 31, 2025

Dear Colleagues,

I am writing to draw your attention to FDA's recommendation that ingestible fluoride drug products – typically available as tablets and drops – should not be given to children under age three or any child at low or moderate risk for tooth decay.

Some epidemiological studies suggest possible associations between fluoride exposure and decreased IQ scores, thyroid function changes, and weight gain. Research has also shown that fluoride alters gut microbiome development. Microbiome alterations are of magnified concern given the early development of the gut microbiome in childhood.

Ingestible fluoride drug products lack proven benefit on primary teeth. Minimal to mild dental fluorosis is a well-established adverse effect of fluoride exposure documented in the literature and the FDA Adverse Event Reporting System. Very mild fluorosis (barely perceptible white spots or lines on the teeth) is most common, whereas mild fluorosis (more pronounced white areas) can occur with cumulative exposure. This recommendation avoids the highest risk window for moderate to severe dental fluorosis at age two for permanent incisors and molar teeth.

In rare cases, moderate to severe dental fluorosis – a discoloration or staining of the teeth – may result when children are exposed to excessive amounts of fluoride. Severe fluorosis results in a failure of the tooth enamel to properly crystallize and may lead to defects that range from barely discernable markings to brown stains and surface pitting.

What are ingestible fluoride drug products?

Although ingestible fluoride drug products have been used since the 1940s, FDA has not reviewed or approved these products for safety, effectiveness or quality. Based on the [scientific evaluation](#) published today, FDA concluded that it should not be used in children under age three or older children who are not at risk of tooth decay. For the same reason fluoride may work to kill bacteria on teeth, it also alters the gut microbiome, which may have broader health implications. While some believe fluoride reduces the risk of dental caries in older children, a Cochrane review of the medical literature concluded that fluoride did not reduce dental caries in developing teeth.

Currently, ingestible single-ingredient unapproved prescription sodium fluoride products are marketed as oral chewable tablets and oral drops with products dosed in the range of 0.25 mg to 1.0 mg per day.

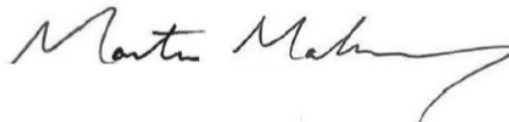
What can health care professionals consider?

Deficiencies in diet and dental hygiene should be addressed with families as a first step to maintain dental health. Topical application is an effective fluoride delivery system, and daily tooth brushing with an appropriate amount of fluoride toothpaste should be recommended.

Thank you for your attention to this important matter.

Sincerely,

Marty

A handwritten signature in black ink, appearing to read "Martin Makary", with a stylized, sweeping flourish at the end.

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs