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Preventing Iron Poisoning in Children

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Efforts to protect children from accidental iron poisoning are getting a boost from new FDA regulations published in the Jan. 15, 1997, Federal Register. Accidental overdose of iron pills is a leading cause of poisoning deaths among young children.

The regulations, which will take effect July 15, 1997, require all iron-containing drugs and dietary supplements to carry a warning about the risk of acute iron poisoning in children under 6 and the need to keep the products out of reach of children.

In addition, most products containing 30 milligrams (mg) or more of iron per dosage unit--such as iron pills for pregnant women--will have to be packaged as individual doses (for example, in blister packages). This is to limit the number of pills or capsules a small child could accidentally consume once the package is opened.

FDA's regulations add to measures already in place, including a U.S. Consumer Product Safety Commission regulation that, since 1987, has required child-resistant packaging for most drugs and food supplements with more than 250 mg of iron per container. Also under way is an FDA education campaign to warn adults to protect children from accidental iron overdose.

Iron Poisoning

Since 1986, poison control centers in the United States have received reports of more than 110,000 incidents of children under 6 accidentally swallowing iron tablets. Some of the children were hospitalized; more than 35 died.

Accidental iron overdose is a leading cause of poisoning deaths in children under 6 in the United States. Almost 17 percent of children's deaths reported to poison control centers between 1988 and 1992 were due to iron poisoning, compared with 12 percent between 1984 and 1987.

The iron products involved in the poisonings ranged from nonprescription daily multivitamin/mineral supplements for children to high-potency prescription iron supplements for pregnant women. In some cases, the iron products were left

within the child's reach in uncapped or loosely capped containers. In others, the child managed to open the container, even though in some cases it appeared to be in child-resistant packaging. In some cases, a sibling opened the container. The children were poisoned after consuming as few as five to as many as 98 iron-containing tablets. Death occurred from ingesting as little as 200 mg to as much as 5,850 mg of iron.

Iron Needs

Iron is an essential nutrient that is lacking in some people's diets. These often include women of childbearing age, including those who are pregnant, all of whom have high iron needs. The National Academy of Sciences' Recommended Dietary Allowance for iron for females between ages 11 and 50 is 15 mg a day and for pregnant women, 30 mg. For adult men and women over 50, the RDA for iron is 10 mg.

Iron deficiency also can affect children, particularly during the rapid growth period from 6 months to 4 years. The RDA for iron for children in this age group is 10 mg.

To prevent iron-deficiency anemia in these populations, doctors often recommend iron supplements. Some iron products are available without a prescription, either as single-ingredient iron pills, which may contain 30 mg or more of iron per dose, or in combination with vitamins or other minerals--for example, pediatric vitamins with iron--which often have less than 30 mg of iron per dose.

Some iron products are available as prescription drugs, such as combination iron and folic acid pills for pregnant women. These usually contain 30 mg or more of iron per dose.

Taken as indicated on the label or as advised by a doctor, these iron products are safe. But when tablets are taken beyond the proper dose in a short period, especially by infants or toddlers, serious injury or death may result.

This raises a public health concern: how to prevent iron poisoning in children while ensuring the availability of iron supplements for those who need them.

FDA Action

In October 1994, FDA proposed regulations to address that issue. The proposal came in recognition of a recent upsurge in iron poisoning cases among children and in response to three citizen petitions submitted to FDA by the American Association of Poison Control Centers, the attorneys general of 34 states, and the Nonprescription Drug Manufacturers Association.

In March 1995, during the proposal's comment period, FDA conducted eight focus group studies in four U.S. cities. The majority of the participants were women between 18 and 35 with children living at home. The studies' objectives were to identify participants' current perceptions and behavior concerning iron-containing products, to test their understanding of several label warning statements, to evaluate which format they felt was best for conveying the warning on the package label, and to evaluate their likely reaction to such a message.

The studies showed that most participants:

- were not aware of the potential for iron-containing products to cause iron poisoning in young children
- kept iron-containing products at home out of reach of children mainly because they regarded them as pill-type products
- overlooked voluntary warnings on iron-containing products because they were not aware of the degree of the health hazard
- differed in their opinions as to what the warning statements should say
- agreed that the warning should be placed on the back of the package with a box around it to make it stand out
- would continue to buy iron-containing products and would handle them properly, now that they knew about their potential danger.

Final Regulations

The final regulations incorporate the studies' findings and numerous comments received by FDA from public health organizations, physicians, manufacturers, and trade organizations.

Under these regulations, packages of all preparations that contain iron for use as dietary supplements or for therapeutic purposes will have to display prominently and conspicuously this boxed warning:

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

The regulation's requirement for unit-dose packaging applies to most of the more potent iron-containing products. Exempt from the unit-dose requirement for one year, however, are products made with carbonyl iron. FDA is allowing this exemption so that manufacturers can collect additional evidence to support their claim that carbonyl iron is less toxic than other common forms of iron, such as ferrous sulfate and ferrous gluconate. FDA believes that because unit-dose packaging will require more time and effort for the child to open, it will reduce the likelihood of the child swallowing a large number of pills.

Education Campaign

In addition to the regulations, FDA is conducting a nationwide public education campaign to protect children from accidental iron overdose. This campaign augments a similar campaign started in 1993 by the Consumer Product Safety Commission and the Nonprescription Drug Manufacturers Association. FDA has produced materials, including a brochure, poster and newspaper columns, informing consumers that:

- iron-containing products can seriously injure and kill young children who accidentally swallow them
- child-resistant packaging of any iron-containing product should be completely reclosed every time it is opened

- iron-containing products should always be kept out of reach of children.

Advice to Adults

Here are other important points FDA wants consumers to know about accidental iron poisoning in children:

Children who are poisoned with iron face both immediate and long-term problems. Within minutes or hours of swallowing iron tablets, they may suffer nausea, vomiting, diarrhea, and gastrointestinal bleeding, which can progress to shock, coma and death. Even if the child appears to recover from these initial problems, severe gastrointestinal bleeding, lethargy, liver damage, heart failure, and coma can occur from 12 hours to two days later. If the victims survive, they can develop other problems, such as gastrointestinal obstruction and more extensive liver damage, three to six weeks after the poisoning.

Even if there are no immediate symptoms, parents should contact a doctor or local poison control center immediately if their child has accidentally swallowed a product that contains iron. Sometimes, serious symptoms do not develop right away, and delayed treatment may not be effective. The telephone number for the closest poison control center is listed with other emergency numbers in the front of phone books.

This FDA backgrounder replaces "Preventing Accidental Iron Poisoning" (BG 94-7, Oct. 5, 1994), which should no longer be used.

BG 97-1

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