

showed transient biochemical hypothyroidism. The effects observed in adults and children were generally of little clinical significance. Observed side effects included gastrointestinal distress in about 2% and rash in about 1%. In two cases, adults with known iodine sensitivity were hospitalized. FDA's position is that the overall benefits of KI far exceed the risks of KI overdosing, especially in children.

11. Should any precautions be considered if KI is recommended for public use?

- Because of possible side effects, individuals with known iodide sensitivity or who have conditions associated with increased risk of iodine hypersensitivity should avoid taking KI;
- Individuals should consult their physicians to determine if they have iodine sensitivity or conditions that may increase their risk of developing iodine hypersensitivity. Such information should be obtained prior to an emergency, since, to be effective, KI needs to be taken within a narrow time window from exposure.
- Because some newborns may develop transient hypothyroidism, newborns given KI should be monitored for hypothyroidism symptoms, and treated if such symptoms are observed. FDA recommends that neonates (newborn to one month), pregnant and lactating women, and those with known iodine sensitivity, should be given priority with regard to other protective measures.

12. What dosage of KI should be administered?

In December 2001, FDA issued a revised guidance document, which recommends the following lowest effective dosages for the different age groups:

Age Group	KI Dosage	# of 130 mg tablets
Adults over 18 years	130 mg	1
Over 3 – 18 years	65 mg	1/2
Over 1 month to 3 years	32 mg	1/4
Birth to 1 month	16 mg	1/8

At the time of this writing, the only currently available FDA-approved over-the-counter formulation is in the 130 mg tablets. Since it is hard to cut many pills, the State Health Commissioner says that, in an emergency, it is safe for children at school or day care centers to take the whole pill. Due to the logistics involved in cutting multiple pills, the New York State Commissioner of Health supports the administration

of the 130 mg tablet for children in settings such as schools or childcare centers in the event of emergencies. This dose is safe and well within the recommended therapeutic range of KI for other indications. The blocking effect of iodide on the thyroid lasts only a few days and any suppressive effect of KI on thyroid function has been shown to be minimal, even in young children. For children or babies who cannot take pills, parents and caregivers can cut or crush the pill to make lower doses. For example, if a 130 mg pill were dissolved in 8 ounces of juice or other liquid, one ounce would contain 16 mg of KI.

13. How often should KI be taken?

Administered KI is effective for about 24 hours. The State or local health department will issue instructions regarding how long to continue taking KI. Once individuals are removed from the areas affected by the release, there is no need to continue taking KI.

14. Does KI come in liquid or pill form?

It could be in either form. For prophylactic use in nuclear power plant emergencies in the US it is marketed in a tablet form. After the 1986 Chernobyl accident, Poland used the liquid form to administer KI to its population. Currently, the FDA has only approved the 130 mg KI in tablet form. New York State has requested FDA to expedite approval of other dosages, as well as liquid form.

15. Is there a shelf life for KI?

The shelf life approved by FDA for different manufacturers of the drug ranges from three to five years. However, if properly stored (protected from air, heat, light and moisture), KI can maintain its form for many years without significant degradation.

16. Does one need a prescription to obtain KI?

No. FDA approved the distribution of KI for prophylactic use as an over-the-counter drug.

17. Can KI be purchased at local pharmacies?

Despite FDA's approval to distribute it over-the-counter, the vast majority of pharmacies do not have it for sale over-the-counter. Individuals can purchase it over the Internet. New York State has requested a supply of KI for individuals who live within ten miles of a nuclear power plant in New York State (Monroe, Orange, Oswego, Putnam, Rockland, Wayne or Westchester Counties). Information regarding pre-distribution and availability will be provided with the annual emergency planning booklet or calendar distributed by either the power company or county government.

For additional information contact:

New York State Department of Health Hotline -800-458-1158 extension 2-7550 or BERP@health.state.ny.us

Other sources of information:

www.fda.gov/cder/guidance/4825fnl.htm