

or reduces the amount of radioiodine that can be taken up by the thyroid.

4. What age group is at the highest risk from exposure to radioiodine?

Children are the group with the highest risk. A significant increase in the incidence of thyroid cancer among children in Belarus, Ukraine and Russia was observed as a result of exposure to radioiodine from the Chernobyl accident. The younger the children, the higher the observed risk. No similar increase was reported for adults.

5. At what radiation dose is KI indicated?

On December 10, 2001, FDA issued new guidance that sets different radiation doses for different risk groups as follows:

Age Groups	Projected Radiation Dose to the Thyroid
0 – 18 years	5 rem
Pregnant and Lactating Women	5 rem
Over 18 – 40 years	10 rem
Over 40 years	500 rem

6. When should KI be taken?

To be most effective, KI should be taken before or shortly after exposure to radioiodine. Even if taken three to four hours after exposure, it still would reduce the uptake of radioiodine by the thyroid. However, its effectiveness would be reduced.

7. How will one know if the use of KI is indicated in an emergency?

The use of KI is only indicated in emergencies where the public is likely to be exposed to radioiodine. The State and County health departments monitor all radiation emergencies and will issue advisories informing the public whether KI should be taken. In those cases

where KI is indicated, the health departments will also issue advisories on when the administration of KI is no longer needed.

8. Is KI effective in all radiation emergencies?

- KI is quite effective in reducing the radiation dose to the thyroid that could result from the intake of radioiodine;
- KI does not protect other organs or tissues;
- KI does not protect against radiation doses received from sources external to the body, such as the radiation dose from the radioactive plume or from exposure to radioactive materials deposited on the ground; and
- KI does not protect against radioactive materials, other than iodine, which are inhaled or ingested.

9. What are other protective measures that can be taken in an emergency?

The existing emergency response plans in New York State rely on evacuation and sheltering-in-place of potentially affected populations to prevent their exposure to the radioactive materials that could be released in an accident. Evacuation would continue to be the primary protective measure in such accidents along with sheltering-in-place of individuals who cannot relocate (captive populations). KI, if used, would only supplement evacuation and sheltering-in-place. Ingestion of contaminated milk or other food products can also lead to significant intake of radioiodine. The primary protective measure for the ingestion pathway is the control of the food supply to prevent ingestion of contaminated products.

10. Does KI have side effects?

A study of a sample of those who were administered KI in Poland, following the Chernobyl accident, provides information on side effects of KI. One in 270 of the newborns

receiving 15 mg of KI 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.

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. Dosages are listed in the table on the next page

KI is currently FDA-approved and available over-the-counter in 65-mg and 130-mg tablets and liquid form. The 65-mg tablets are larger than the 130-mg tablets and scored in quarters. Dosing at the FDA recommended level is much easier with the liquid or 65-mg tablets. The pills can either be cut on the score lines or crushed to make lower doses, which will help parents and caregivers measure the right dose for younger children or babies, who cannot take pills. 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.

Efforts should be made to dose at the FDA-recommended level, especially for neonates. 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. Children 12 years and under should take one 65-mg tablet. Children over 12 years or over 150 pounds should take one 130-mg tablet or two 65-mg tablets. If the appropriate dosage is not available, the New York State Commissioner of Health supports the administration of the 130-mg tablet for children 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. FDA’s position is that the overall benefits of KI far exceed the risks of KI overdosing, especially in children.

Recommended Doses of KI for Different Risk Groups				
Age Group	KI Dosage	Number of ml liquid (65 mg/ml)	Number of 65-mg tablets	Number of 130-mg tablets
Adults over 18 years	130 mg	2	2	1
Over 12 -18 years and over 150 pounds	130 mg	2	2	1
Over 12 -18 years and less than 150 pounds	65 mg	1	1	1/2
Over 3 -12 years	65 mg	1	1	1/2
Over 1 month to 3 years	32 mg	0.5	1/2	1/4
Birth -1 month	16 mg	0.25	1/4	1/8

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 both liquid and tablet form. After the 1986 Chernobyl accident, Poland used the liquid form to administer KI to its population. KI is currently FDA-approved and available over-the-counter in 65-mg and 130-mg tablets and liquid form

15. Is there a shelf life for KI?

The shelf life approved by FDA for different manufacturers of the drug ranges from five to seven 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 Infoline at 1-800-458-1158, extension 2-7550 or e-mail BERP@health.ny.gov

Other sources of information:

- <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080542.pdf>
- <https://www.fda.gov/drugs/emergencypreparedness/bioterrorismmanddrugpreparedness/ucm072265.htm>
- <https://www.fda.gov/drugs/emergencypreparedness/bioterrorismmanddrugpreparedness/ucm072261.htm>
- <https://emergency.cdc.gov/radiation/ki.asp>
- http://www.who.int/ionizing_radiation/pub_meet/tech_briefings/potassium_iodide/en/
- http://www.health.ny.gov/environmental/radiological/potassium_iodide/



Use of Potassium Iodide During Radiological Emergencies Information for the Public

1. **Purpose**
In December 2001, the Food and Drug Administration (FDA) issued new recommendations for the administration of potassium iodide (KI) to the general public as a supplement to evacuation and sheltering during a radiological emergency. The State of New York in turn has revised its 1982 KI Policy to reflect this new guidance. This fact sheet presents general information on KI for members of the public.
2. **What is potassium iodide and what is it used for?**
Potassium iodide (KI) is a chemical compound that can be used to protect the thyroid gland from possible radiation injury caused by radioactive iodine (radioiodine). Some radiological emergencies may release large amounts of radioiodine to the environment. Since iodine concentrates in the thyroid gland, inhalation or ingestion of food contaminated with the radioiodine can lead to radiation injury to the thyroid. This includes increased risk of thyroid cancer and other thyroid diseases. Thyroid cancer is curable in most cases, but taking measures that reduce the chance of developing cancer are still preferable.
3. **How does KI work?**
Taking KI saturates the thyroid gland with stable (non-radioactive) iodine. This prevents