Frequently Asked Questions on Potassium Iodide (KI)

In December 2001, the Food and Drug Administration (FDA) issued a final Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies) (/media/72510/download) (PDF - 40 KB). The objective of the document is to provide guidance to other Federal agencies, including the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC), and to state and local governments regarding the safe and effective use of potassium iodide (KI) as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The adoption and implementation of the recommendations are at the discretion of the state and local governments responsible for developing regional emergency-response plans related to radiation emergencies. The recommendations in the guidance address KI dosage and the projected radiation exposure at which the drug should be used. This guidance updates FDA's 1982 recommendations.

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1. What does potassium iodide (KI) do

The effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well established. When administered in the recommended dose, KI is effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodines. KI floods the thyroid with non-radioactive iodine and prevents the uptake of the radioactive molecules, which are subsequently excreted in the urine.

2. Can potassium iodide (KI) be used to protect against radiation from bombs other than radioactive iodine, such as radiation from a dirty bomb?

Potassium iodide (KI) works only to prevent the uptake of radioactive iodine into the thyroid gland. It is not a general radioprotective agent.

3. Who really needs to take potassium iodide (KI) after a nuclear radiation release?

The FDA guidance prioritizes groups based on age, which is the primary factor for determining risk for radioiodine-induced thyroid cancer. Those at highest risk are infants and children, as well as pregnant and nursing females because of the potential for KI to suppress thyroid function in the developing fetus and the newborn. The recommendation is to treat them at the lowest threshold (with respect to predicted radioactive dose to the thyroid). Anyone over 18 years old and up to 40 years old should be treated at a slightly higher threshold. Finally, anyone over 40 years old should be treated with KI only if the predicted exposure is high enough to destroy the thyroid and induce lifelong hypothyroidism (thyroid deficiency).

4. What potassium iodide (KI) products are currently available?

Only KI products that are FDA-approved may be legally marketed in the United States. As of March 2022, these KI products are FDA-approved and are available without a prescription:

- iOSAT tablets, 130mg, from Anbex, Inc.
- iOSAT tablets, 65mg, from Anbex, Inc.
- ThyroSafe tablets, 65mg, from BTG INTERNATIONAL, Inc.
- Potassium Iodide Oral Solution USP, 65mg/mL, from Mission Pharmacal Company

5. What dosages of potassium iodide (KI) should be taken for specific exposure levels

FDA recommends the following dosing of KI for thyroid blocking following radioactive exposure:

Threshold Thyroid Radioactive Exposures and
Recommended Doses of KI for Different Risk Groups

	Predicted Thyroid gland exposure (cGy)	KI dose (mg)	Number or fraction of 130 mg tablets	Number or fraction of 65 mg tablets	Milliliters (mL) of oral solution, 65 mg/mL***
Adults over 40 years	> 500	130	1	2	2 mL
Adults over 18 through 40 years	> 10	130	1	2	2 mL
Pregnant or Lactating Women	> 5	130	1	2	2 mL
Adolescents, 12 through 18 years*	> 5	65	½	1	1 mL
Children over 3 years through 12 years	> 5	65	½	1	1 mL
Children over 1 month through 3 years	> 5	32	Use KI oral solution**	½	0.5 mL
Infants birth through 1 month	> 5	16	Use KI oral solution**	Use KI oral solution**	0.25 mL

* Adolescents approaching adult size (> 150 lbs or > 70 kg) should receive the full adult dose (130 mg)

** Potassium iodide oral solution is supplied in 1 oz (30 mL) bottles with a dropper marked for 1, 0.5, and 0.25 mL dosing. Each mL contains 65 mg potassium iodide.

*** See the Home Preparation and Dosing Instructions for Making KI Solution using KI Tablets for the Emergency Administration of Potassium Iodide to Infants and Small Children (/drugs/bioterrorism-and-drug-preparedness/potassium-iodide-ki)

6. When should I take potassium iodide (KI)?

KI should not be taken as a preventative before radiation exposure. After a radiological or nuclear event in the United States, local public health or emergency management officials will tell the public if there is a need to take KI or other protective actions. After an event in the US, you should follow the instructions given to you by these local authorities. Taking a higher dose of KI, or taking KI more often than recommended, does not offer more protection and can cause severe illness or death.

7. For how long should I take potassium iodide (KI)?

Since KI protects for approximately 24 hours, it should be dosed daily until the risk no longer exists. Priority with regard to evacuation and sheltering should be given to pregnant females and neonates because of the potential for KI to suppress thyroid function in the fetus and

neonate. Unless other protective measures are not available, we do not recommend repeat dosing in pregnant females and neonates.

8. Who should not take potassium iodide (KI) or should have restricted use?

Persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity. A seafood or shellfish allergy does not necessarily mean that you are allergic or hypersensitive to iodine. People with nodular thyroid with heart disease should not take KI. Individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis should be treated with caution -- especially if dosing extends beyond a few days. If you are not sure if you should take KI, consult your health care professional.

9. What are the side effects of potassium iodide (KI)?

Side effects are unlikely when KI is used at the recommended dose and for a short time. The following are possible side effects:

- Skin rashes
- Swelling of the salivary glands
- “Iodism” (metallic taste, burning mouth and throat, sore teeth and gums, symptoms of a head cold, and sometimes upset stomach and diarrhea)
- An allergic reaction can have more serious symptoms. These include fever and joint pains; swelling of parts of the body (face, lips, tongue, throat, hands, or feet); trouble breathing, speaking, or swallowing; wheezing or shortness of breath. Severe shortness of breath requires immediate medical attention.

10. Should I check with my doctor before I take potassium iodide (KI)?

KI is available without a prescription. However, if you have any health concerns or questions, you should check with your doctor before you take KI.

11. As a doctor, should I recommend potassium iodide (KI) for my patients who request it?

As with any drug, physicians should understand the risks and benefits of KI before recommending it or prescribing it to patients. We recommend that physicians read our 2001 guidance Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (/media/72510/download) for more information. The FDA guidance discusses the rationale and methods of safe and effective use of KI in radiation emergencies. It specifically addresses threshold predicted thyroid radioiodine exposure for intervention and dosing by age group. The recommendations for intervention are based on categories of risk for thyroid cancer, with the

young prioritized because of increased sensitivity to the carcinogenic effects of radioiodine. We also recommend our 2002 guidance KI in Radiation Emergencies—Questions and Answers (/media/72515/download) . This guidance provides answers to questions that FDA has received as state and local governments develop emergency response plans involving the use of KI to protect against the effects of radioactive iodine.

12. Should I buy potassium iodide (KI) to keep on hand

KI works best if used within 3-4 hours of exposure. Although FDA has not made specific recommendations for individual purchase or use of KI, the Nuclear Regulatory Commission (NRC) supplies KI tablets, in accordance with FDA dosing guidelines, to states (including tribal governments) that request it for populations within the 10-mile emergency planning zone of a nuclear power plant.

NRC Reference: Use of Potassium Iodide (https://www.nrc.gov/about-nrc/emerg-preparedness/about-emerg-preparedness/potassium-iodide-use.html)

13. How do I know that potassium iodide (KI) will be available in case of an emergency

FDA will continue to work with interested pharmaceutical manufacturers to assure that high quality, approved, safe, and effective KI products are available for purchase by consumers, by state and local authorities, and by federal government agencies electing to do so.