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## Drugs

### 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 (PDF - 40KB)<sup>1</sup>. 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?

Potassium iodide (KI) works only to prevent the thyroid from uptaking radioactive iodine. 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 primarily determines risk for radioiodine-induced thyroid cancer. Those at highest risk are infants and children, as well as pregnant and nursing females, and the recommendation is to treat them at the lowest threshold (with respect to predicted radioactive dose to the thyroid). Anyone over age 18 and up to age 40 should be treated at a slightly higher threshold. Finally, anyone over 40 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?

As of January 2005, Iosat, ThyroSafe, and ThyroShield are FDA approved KI products. You can find out more about these products at [Drugs@FDA](#)<sup>2</sup>. Please be aware that only the KI products approved by FDA may be legally marketed in the United States.

#### 5. How are these products available?

In addition to distributing to state, local and federal agencies, Anbex, Inc., has made Iosat Tablets (130 mg) available to the general public via the Internet. For further information on KI products, you can contact these companies as noted below:

- Anbex, Inc. for Iosat Tablets (130 mg) at 212-580-2810 (M-F 9am-5pm), at 1-866-463-6754 (other times), or

<http://www.anbex.com><sup>3</sup> <sup>4</sup>

- Recip for ThyroSafe Tablets (65 mg) at 1-866-849-7672 or <http://www.thyrosafe.com/recipe.html><sup>5</sup> <sup>6</sup>
- Fleming & Company, Pharmaceuticals for ThyroShield Solution at 636-343-5306 or <http://www.flemingpharma.com><sup>7</sup> <sup>8</sup> or <http://www.thyrosshield.com><sup>9</sup> <sup>10</sup>

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

FDA recommends the following dosing of KI for thyroid blocking:

### 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***
<b>Adults over 40 years</b>	$\geq 500$	130	1	2	2 mL
<b>Adults over 18 through 40 years</b>	$\geq 10$	130	1	2	2 mL
<b>Pregnant or Lactating Women</b>	$\geq 5$	130	1	2	2 mL
<b>Adolescents, 12 through 18 years*</b>	$\geq 5$	65	$\frac{1}{2}$	1	1 mL
<b>Children over 3 years through 12 years</b>	$\geq 5$	65	$\frac{1}{2}$	1	1 mL
<b>Children 1 month through 3 years</b>	$\geq 5$	32	Use KI oral solution**	$\frac{1}{2}$	0.5 mL
<b>Infants birth through 1 month</b>	$\geq 5$	16	Use KI oral solution**	Use KI oral solution**	0.25 mL

\* Adolescents approaching adult size ( $\geq 150$  lbs) 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 Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Children<sup>11</sup>.

## 7. How long should potassium iodide (KI) be taken?

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 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 healthcare professional.

## 9. What are the side effects ?

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 first?**

Potassium iodide (KI) is available over-the-counter (OTC). However, if you have any health concerns or questions, you should check with your doctor.

**11. As a doctor, should I be recommending 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 guidance for more information. It is available on the FDA Drug Guidances<sup>12</sup> web page, under procedural guidance #18. 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.

**12. Should I go out and 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 has contracted to purchase KI for states with nuclear reactors and states that have population within the 10-mile emergency planning zone, e.g., Delaware or West Virginia.

**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, 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.

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1. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080542.pdf>
2. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>
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