Frequently Asked Questions on Potassium Iodide (KI)

In November 2001, the Food and Drug Administration (FDA) issued a final "Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies." 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.

1. What does potassium iodide (KI) do?
2. Can potassium iodide (KI) be used to protect against radiation from bombs other than radioactive iodine?
3. Who really needs to take potassium iodide (KI) after a nuclear radiation release?
4. What potassium iodide (KI) products are currently available? (3/18/2003)
5. How are these products available?
6. What dosages of potassium iodide (KI) should be taken for specific exposure levels?
7. How long should potassium iodide (KI) be taken?
8. Who should not take potassium iodide (KI) or have restricted use?
9. What are the possible risks and side effects of taking potassium iodide (KI)?
10. Should I check with my doctor first?
11. As a doctor, should I be recommending potassium iodide (KI) for my patients who request it?
12. Should I go out and buy potassium iodide (KI) to keep on hand?
13. How do I know that potassium iodide (KI) will be available in case of an emergency?

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?
(3/18/2003)

As of March 2003, the FDA has approved 3 KI products (Thyro-Block, Iosat, and ThyroSafe). You can find out more about these KI products and any other KI products the agency may approve in the future in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) at http://www.fda.gov/cder/ob/default.htm. Please be aware that only the KI products approved by FDA may be legally marketed in the United States.

Back to Top

5. How are these products available?

MedPointe, Inc., is distributing Thyro-Block strictly to state, local, and federal agencies, nuclear power plants, and hospitals. In addition to distributing to state, local and federal agencies, Anbex, Inc., has made its product available to the general public via the Internet. For further information, you can contact Anbex, Inc., at (727) 784-3483 and MedPointe, Inc. at (609) 655-6000.

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

Exposures greater than 5 cGy:
Birth through 2 mos. - 16 mg.
1 mo. through 3 yrs. - 32 mg.
3 yrs through 18 yrs. - 65 mg. (Adolescents>150 pounds should take adult dose.)

Exposures greater than 10 cGy:
18 yrs through 40 yrs. - 130 mg

Exposures greater than 500 cGy:
Adults over 40 yrs - 130 mg.

Back to Top

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. Individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis should be treated with caution -- especially if dosing extends beyond a few days.

9. What are the possible risks and side effects of taking potassium iodide (KI)?

Thyroidal side effects of KI at recommended doses rarely occur in iodine-sufficient populations such as the U.S. As a rule, the risk of thyroidal side effects is related to dose and to the presence of underlying thyroid disease (e.g., goiter, thyroiditis, Graves'). FDA recommends adherence to the Guidance for intervention threshold and dose, though we recognize that the exigencies of any particular emergency situation may mandate deviations from those recommendations. With that in mind, it should be understood that as a general rule, the risks of KI are far outweighed by the benefits with regard to prevention of thyroid cancer in susceptible individuals.

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.

Back to Top

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 website at http://www.fda.gov/cder/guidance/index.htm 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.

Back to Top Drug Preparedness and Response

FDA/Center for Drug Evaluation and Research
Last Updated: March 18, 2003
Originator: OTCOM/DLIS
HTML by CSA, SJW