Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Children

INTRODUCTION

In the event of accidental release of radioactive iodine into the atmosphere, potassium iodide (KI) is recommended for use as an aid to other emergency measures, such as evacuation and food control measures. When used correctly, potassium iodide can prevent or reduce the amount of radioactive iodine taken up by the thyroid gland. The government stockpiles potassium iodide for emergency uses, such as in the event of an unexpected release of radioactive iodide.

Potassium iodide (KI) is stockpiled as tablets because tablets are easier to store; however, infants and small children cannot swallow tablets. In an emergency such as an unexpected release of radioactive iodine, the potassium iodide tablets may need to be given to infants and children by their parents or caregivers. Since potassium iodide dissolved in water may be too salty to drink, the Food and Drug Administration (FDA) is providing parents or caregivers with instructions on how to mix the potassium iodide tablets with a food or a drink to disguise the taste so infants and small children will take the medicine in an emergency. To see what worked best to disguise the taste of potassium iodide, FDA asked adults to taste the following six mixtures of potassium iodide and drinks.

Water
Low fat white milk
Low fat chocolate milk
Orange juice
Flat Soda (For example, cola)
Raspberry syrup

The mixture of potassium iodide with raspberry syrup disguises the taste of potassium iodide best. The mixtures of potassium iodide with low fat chocolate milk, orange juice, and flat soda (for example, cola) generally have an acceptable taste. Low fat white milk and water did not hide the salty taste of potassium iodide.

INGREDIENTS AND SUPPLIES NEEDED TO PREPARE POTASSIUM IODIDE (KI) TABLETS

Potassium iodide (KI) 130 mg tablet
Metal teaspoon
Small bowl
One of the drinks from the list above or infant formula.

PREPARATION FOR 130 MG POTASSIUM IODIDE TABLET

1. Grinding the potassium iodide tablet into powder

- Put **one** 130mg potassium iodide tablet into a small bowl and grind it into a fine powder using the back of the metal teaspoon against the inside of the bowl. The powder should not have any large pieces.

2. Mixing potassium iodide powder into a drink

- Add four teaspoonfuls of water to the potassium iodide powder in the small bowl. Use a spoon to mix them together until the potassium iodide powder is dissolved in the water.

3. Mix drink of choice with potassium iodide powder and water solution

- Add four teaspoonfuls of drink to the potassium iodide powder and water mixture described in Step 2.

The amount of potassium iodide in the drink is 16.25 mg per teaspoon. The number of teaspoonfuls of the drink to give your child depends on your child's age. There is a chart at the end of these directions to tell you how much to give your child.

The potassium iodide in any of the six drinks listed above and infant formulas will keep for up to seven days in the refrigerator. FDA recommends that the potassium iodide drink mixtures be prepared weekly; unused portions should be discarded.

ADMINISTRATION

FDA recommends doses for potassium iodide based on age, predicted thyroid exposure to radioiodines, and –for women -- whether the woman is pregnant or nursing (see Table 1). Adults over 18 years of age and pregnant or lactating women should take the potassium iodide 130-mg tablet. Infants, children, and adolescents through 18 years of age should take potassium iodide in a drink prepared according to the procedure described above. Table 2 shows how many teaspoonfuls of potassium iodide mixture to give to an adolescent, child, or infant. The dose of potassium iodid**e** should be taken once a day until a risk of significant exposure to radioiodines no longer exists.

Table 1. Threshold thyroid radioactivity exposures and the recommended dose of Potassium iodide (KI) for different groups[1].

If you are:	And your predicted Thyroid Exposure is	Then you should take:	Number of 130 mg tablets
An adult over the age of 40	Equal to or greater than 500 centi-grays (cGy)	a 130 mg dose of potassium Iodide (KI)	1
An adult between the ages of 18 and 40	Equal to or greater than 10 cGy		
A pregnant or lactating woman	Equal to or greater than 5cGy		

[1] FDA, Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies, December 2001.

Table 2. Recommended doses of KI for adolescents, children, and infants with predicted thyroid radioactivity exposures equal to or greater than 5 cGy[1], using 130 mg tablet preparations.

If your child is:	Give your child this amount of Potassium Iodide (KI) *	Which is
An adolescent between 12 and 18 years old**	4 **teaspoonfuls** (NOT tablespoonfuls)	65 mg of potassium iodide (KI)
Between 4 and 12 years old	4 **teaspoonfuls** (NOT tablespoonfuls)	65 mg of potassium iodide (KI)
Over 1 month through 3 years	2 **teaspoonfuls** (NOT tablespoonfuls)	32.5 mg of potassium iodide (KI)
An infant from birth through 1 month	1 **teaspoonful** (NOT a tablespoonful)	16.25 mg of potassium iodide (KI)

* This is the amount to give your child for **one** dose. You should give your child one dose each day.

** Adolescents approaching adult size [equal to or greater than 154 pounds (70 kg)] should receive the full adult dose (130 mg tablet or 8 teaspoonfuls of KI mixture).

[1] FDA, Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies, December 2001.original table below

PREPARATION FOR 65 MG POTASSIUM IODIDE TABLET

If you have potassium iodide 65 mg tablets, then prepare the mixture as described below:

1. Grinding the potassium iodide 65 mg Tablet into Powder

- Put **one** 65mg potassium iodide tablet into a small bowl and grind it into a fine powder using

the back of the metal teaspoon against the inside of the bowl. The powder should not have any large pieces.

2. Mixing potassium iodide Powder into a Drink

- Add four teaspoonfuls of water to the potassium iodide powder in the small bowl. Use a spoon to mix them together until the potassium iodide powder is dissolved in the water.

3. **Mix drink of choice with potassium iodide powder and water solution**

- Add four teaspoonfuls of drink to the potassium iodide powder and water mixture described in Step 2.

The amount of potassium iodide in the drink is 8.125 mg per teaspoon. The number of teaspoonfuls of the drink to give your child depends on your child's age. Table 3 shows how many teaspoonfuls of potassium iodide mixture to give to an adolescent, child, or infant. **Please pay attention to the number of teaspoonfuls recommended when using a potassium iodide 65 mg tablet as it is different from the number of teaspoonfuls given when using a potassium iodide 130 mg tablet.**

Table 3. Recommended doses of KI for children and infants with predicted thyroid radioactivity exposures equal to or greater than 5 cGy[1], using 65 mg tablet preparations.

If your child is:	Give your child this amount of potassium iodide (KI) *	Which is
Between 4 and 12 years old	8 **teaspoonfuls** (NOT tablespoonfuls)	65 mg of potassium iodide (KI)
Over 1 month through 3 years	4 **teaspoonfuls** (NOT tablespoonfuls)	32.5 mg of potassium iodide (KI)
An infant from birth through 1 month	2 **teaspoonfuls** (NOT tablespoonfuls)	16.25 mg of potassium iodide (KI)

* This is the amount to give your child for **one** dose. You should give your child one dose each day.

[1] FDA, Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies, December 2001.

Information on Obtaining Approved Potassium Iodide Pills

If you wish to obtain potassium iodide pills approved by the FDA, you may do so by contacting:

- Anbex for IOSTAT Tablets at 212-580-2810 or via Internet http://www.anbex.com

- MedPointe Inc. for THYRO-BLOCK at 732-564-2200 or via Internet http://www.medpointeinc.com

If you have any questions about the availability of potassium iodide tablets in your area, please contact your state officials.

REFERENCES

Palatability Evaluations of Potassium Iodide Solid Dosage Tablets ground and mixed in Drinks[1]

Francis R. Pelsor, Nakissa Sadrieh, and Stella G. Machado.
U.S. Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857.

ABSTRACT

Objective. To evaluate the hypothesis that the potassium iodide (KI) 130 mg tablet, once ground and mixed with appropriate drinks, could be taken orally with reasonable palatability. *Methods.* Thirty healthy adult male and female volunteers completed the taste study in a blinded fashion. The taste and aftertaste of the following drinks each containing KI were evaluated: water (negative control), low fat milk, low fat chocolate milk, orange juice, soda (cola, flat), and raspberry syrup. *Results.* Taste ranking of all six preparations, highest to lowest, was as follows: raspberry syrup, low fat chocolate milk, simple syrup, orange juice, flat cola, low fat milk, and water. The preparations of raspberry syrup, low fat chocolate milk, orange juice, and cola (flat) have acceptable taste and palatability. *Conclusions.* The results from this study confirm our hypothesis that the KI tablet, once ground and mixed with drinks, can have acceptable palatability. It appears that raspberry syrup has a high capacity to mask the saltiness while low fat milk has little capacity to cover the saltiness of KI.

[1]This work was completed through a FDA contract with the Department of Pharmaceutical Sciences, College of Pharmacy, University of Tennessee, Memphis, TN 38163, Arthur B. Straughn (Principal Investigator).

Stability and Dose Uniformity Evaluations of Potassium Iodide Solid Dosage Tablets mixed in Drinks

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Government stockpiles of drugs needed for bioterrorism include solid oral dosage forms. In order to give these drugs to children in an emergency, the solid dosage forms need to be ground and mixed with appropriate foods or drinks. To be effective in children, the drug/food or drug/drink mixture must have good stability and dose uniformity and have reasonable taste. For this study, stability and dose uniformity were examined for potassium iodide (KI) 130-mg tablets mixed with various drinks. Tablets were dissolved in water to yield 65 mg KI/5 mL or 32.5 mg KI/5 mL stock solutions.

Dose uniformity was determined by mixing one teaspoon of KI stock solution (65 mg/5 mL) with one teaspoon of water. Two analysts each repeated the procedure five times. The average amount (±1SD) of KI per teaspoonful (or medicinal dispensing container) was 32.0 (±2.6) mg.

The results show that the procedure for mixing KI in water is acceptable for administration of ¼ tablet (Range: 88%-112% of desired amount).

Seven-day stability in the refrigerator (2 – 8 ºC) of KI added to each of the following preparations were evaluated: water, orange juice, soda (cola), simple syrup with raspberry flavor, low fat milk, low fat chocolate milk, and infant formula. The results of recovery[1] and stability testing of KI mixtures are shown in Table 1.

[1] Recovery is the ratio (expressed as percent) of the amount of active drug measured in the test to the amount of active drug added to the mixture.

Table 1: Recovery and stability of KI (130 mg tablet) mixed with various drinks.

Drinks	**Dose (mg)**	**Original % Recovery**	**% Recovery after 7 days (Temperature, 2-8 ºC)**
Stock Solution (65 mg/5 mL)		97.7	101.5
Water	32	102.8	102.9
Water	16	104.9	100.0
Orange Juice	32	100.4	101.4
Orange Juice	16	102.9	97.9
Soda (cola)	32	104.7	103.2
Soda (cola)	16	101.5	99.6
Raspberry Syrup	32	105.0	104.8
Raspberry Syrup	16	102.6	102.0
Low Fat Milk	32	106.1	99.9
Low Fat Milk	16	98.0	100.2
Low Fat Chocolate Milk	32	103.2	102.6
Low Fat Chocolate Milk	16	100.3	99.4
Infant Formula	32	104.6	103.0
Infant Formula	16	100.5	99.6

Good original recoveries (all >97% recovery) and 7-day stability (all >97% recovery) (Refrigerated, 2 – 8 ºC) were seen for KI tablets dissolved in water and mixed with all seven drinks.