Take potassium iodide (KI) only when public officials tell you. In a nuclear radiation emergency, radioactive iodine. Therefore, KI should be used along with other emergency measures that will be hours. Do not take it more often. More KI will not help you. Too much KI may increase the chances of side effects. Do not take this medicine if you know you are allergic to iodine (see SIDE EFFECTS below).

DESCRIPTION
ThyroSafe® (Potassium Iodide Tablets, USP) is a thyroid blocking medicine that is used in a nuclear radiation emergency only.

INDICATIONS
Use only as directed by public officials if a nuclear radiation emergency happens.

Adults over 18 years

Children over 12 years to 18 years who weigh at least 150 pounds

Children over 12 years to 18 years who weigh less than 150 pounds

Children over 3 years to 12 years

Children over 1 month to 3 years

Babies at birth to 1 month

HOW TO USE

Making a Potassium Iodide Liquid Mixture:

1. Put 65 mg KI tablet into a small bowl and grind it into a fine powder using the back of a metal spoon.

2. Add 4 teaspoons of water to the crushed KI powder in the bowl and mix until the KI powder is dissolved in the water.

3. Taste the amount of powder to be used in one single dose in your child's age as described in the following chart:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Number of Teaspoons to Give</th>
<th>KI Powder Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 1 month</td>
<td>2 teaspoons</td>
<td>15 mg</td>
</tr>
<tr>
<td>Over 1 month to 3 years</td>
<td>4 teaspoons</td>
<td>32.5 mg</td>
</tr>
<tr>
<td>Over 3 to 12 years</td>
<td>8 teaspoons</td>
<td>65 mg</td>
</tr>
<tr>
<td>Over 12 to 18 years</td>
<td>8 teaspoons</td>
<td>65 mg</td>
</tr>
</tbody>
</table>

The number of teaspoons of the drink to give your child depends on your child's age as described above.

The amount of KI (65 mg tablet) in the drink when mixed as described above is 8.125 mg per teaspoon.

Possible side effects include: swelling of the salivary glands, nausea, vomiting, diarrhea, stomach ache, fever, headache, metallic taste, and allergic reactions. Allergic reactions can include:

· swelling of various parts of the body such as the face, lips, tongue, throat, hands or feet
· fever with joint pain
· trouble breathing, speaking or swallowing
· shortness of breath or wheezing
· swelling of the lips, tongue or throat
· skin rash
· irregular heart beat or chest pain
· swelling of the face, hands or feet
· fever and joint pain
· skin rash
· swelling of the salivary glands

WHAT TO DO IF SIDE EFFECTS OCCUR
Stop taking KI and call a doctor if you have one or more of the following symptoms:

- Irregular heart beat or chest pain
- Swelling of the face, hands or feet
- Fever and joint pain
- Skin rash

WARNING
People who are allergic to iodine. In rare cases, taking iodide may cause overactivity of the thyroid gland, underactivity of the thyroid gland, or enlargement of the thyroid gland (goiter). Symptoms of an overactive thyroid gland may include an increased rate of heart beat, trouble breathing, sweating, feeling hot, and weight loss. People who are allergic to iodine may have similar side effects when taking iodide. People who have had thyroid disease may also have a higher risk of these side effects. People who are allergic to iodine may have an increased risk of developing thyroid disease.

WHEN TO USE

Step 1: Ask your doctor or pharmacist about the following symptoms:
- Weight loss
- Heat intolerance
- Fast heart rate
- Nervousness
- Sweating
- Trouble sleeping
- Muscle weakness
- Increased appetite
- Wrist pain
- Thinning hair
- Menstrual changes

Step 2: Take ThyroSafe® (Potassium Iodide Tablets, USP) as directed above and call a doctor if you need to take KI for more than a few days.

HOW TO STORE

Store in a cool, dry place and keep out of the reach of children.
Take potassium iodide (KI) only when public officials tell you. In a nuclear radiation emergency, radioactive iodine may be released in the air. Therefore, KI should be used along with other emergency measures that will be recommended to you by public officials. If you are told to take this medicine, take it 1 time every 24 hours. Do not take it more often. More KI will not help you. Too much KI may increase the chances of side effects. Do not take this medicine if you know you are allergic to iodine (see SIDE EFFECTS below).

### INDICATIONS

ThyroSafe is indicated for use in a radiation emergency only. Use only as directed by public officials if a nuclear radiation emergency happens.

### Dose:

- **Adults over 18 years:** 2 tablets (whole or crushed) every day (130 mg)
- **Children over 12 years to 18 years who weigh at least 150 pounds:** 2 teaspoons every day (16.25 mg)
- **Children over 12 years to 18 years who weigh less than 150 pounds:** 4 teaspoons every day (32.5 mg)

Following are the amounts of the drink to give your child depending on your child's age as described in the Consumer Package Insert.

<table>
<thead>
<tr>
<th>Child's Age</th>
<th>Give your child this amount in teaspoons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 1 month to 3 years old</td>
<td>4 teaspoons will give you a 32.5 mg dose</td>
</tr>
<tr>
<td>Over 3 to 12 years old</td>
<td>8 teaspoons will give you a 65 mg dose</td>
</tr>
</tbody>
</table>

The amount of KI (65 mg tablet) in the drink when mixed as described above is 8.125 mg per teaspoon. The number of teaspoons of the drink is your child's daily dose as directed by public officials following the above formula.

### HOW AND WHEN TO TAKE POTASSIUM IODIDE

1. Put one 65 mg KI tablet into a small bowl and grind it into a fine powder using the back of a metal spoon (not a fork) against the inside of the bowl. The powder should not have any large pieces.
2. Add 4 teaspoons of water to the crushed KI powder in the bowl and mix until the KI powder is dissolved in the water. Mixtures be prepared weekly. Throw away unused portions.
3. Take the KI water mixture solution made in step 2 and mix it with 4 teaspoons of low fat white or nonfat milk. Mix well.

### DOSE FORMS

- ThyrOSafe tablet contains 65 mg of potassium iodide. (Abbreviated KI)

### WARNING

- Do not take KI if you know you are allergic to iodine.
- Do not take if you have a nodular thyroid condition such as multinodular goiter with or without enlargement of the thyroid gland (goiter). Symptoms of an overactive thyroid gland may include an irregular heart beat or chest pain.
- Babies under 1 month of age are more likely to get an underactive thyroid gland (hypothyroidism).

### SIDE EFFECTS

- Possible side effects include: swelling of the salivary glands, nausea, vomiting, diarrhea, stomach ache, heartburn.
- More serious side effects include: swelling of various parts of the body such as the face, hands or feet.
- Get medical attention right away if you have trouble breathing, speaking or swallowing; wheezing; shortness of breath; swelling of the face, hands or feet.

### HOW POTASSIUM IODIDE WORKS

Certain forms of iodine help your thyroid gland work right. Most people get the iodine they need from foods and beverages. In a nuclear radiation emergency, radioactive iodine may be released in the air. Therefore, KI should be used along with other emergency measures that will be recommended to you by public officials.

### WHO SHOULD NOT TAKE POTASSIUM IODIDE

- People who are allergic to iodine.
- People who have had hyperthyroidism or hyperlipidemia.
- People who have had thyroid cancer (in the past or present).
- People with history of thyroid disorder who have not had radioactive iodine treatment.

### HOW SUPPLIED

- ThyrOSafe tablets are white, round, cross-scored tablets. Packages of 10 and 20 tablets. Each white, round, cross-scored tablet contains 65 mg of potassium iodide (potassium iodide, USP) tablets. Packages of 10 and 20 tablets. Each white, round, cross-scored tablet contains 65 mg of potassium iodide (potassium iodide, USP) tablets.

### Date 2008-10-07

Manufactured by Recipharm Stockholm AB, Sweden, for Recipharm Inc, USA. 800-849-7672.