Consumer Package Insert

ThyroSafe®
(Potassium Iodide Tablets USP, 65 mg)
(Abbreviated KI)

Take potassium iodide (KI) only when public officials tell you. In a nuclear radiation emergency, radioactive iodine could be released into the air. KI protects only the thyroid gland from uptake of radioactive iodine. Therefore, KI should not 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).

DESCRIPTION
Each white, round, cross-scored ThyroSafe® tablet contains 65 mg of potassium iodide.

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

DIRECTIONS FOR USE
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
1 tablet (whole or crushed) or 8 teaspoons every day (65 mg)

who weigh less than 150 pounds
Children over 3 years to 12 years
1 tablet (whole or crushed) or 8 teaspoons every day (65 mg)

who weigh at least 150 pounds
Children over 1 month to 3 years
4 teaspoons every day (32.5 mg)

Babies at birth to 1 month
2 teaspoons every day (16.25 mg)

Tablets can be crushed and mixed in many liquids. To take the tablet in liquid solution, use dosing directions under Making a Potassium Iodide Liquid Mixture.

Take KI every day (every 24 hours) as directed by public officials. Do not take more than 1 dose in 24 hours. More will not help you. Too much medicine may increase the chances of side effects.

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Stop taking KI and get medical help right away if you have one or more of the following symptoms:
· trouble breathing, speaking or swallowing
· shortness of breath or wheezing
· swelling of the lips, tongue or throat
· irregular heart beat or chest pain

HOW SUPPLIED

Manufactured by Recipharm Stockholm AB, Sweden, for Recipharm Inc, USA. l-866-849-7672.


Revised 2008-10-07

Date 2008-10-07

Approved by: Jennie Barbieri

Anette Nyhlén

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### DIRECTIONS FOR USE

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

**Dose:**
- **Children over 3 years to 12 years:** 1 tablet (whole or crushed) or 8 teaspoons every day (65 mg)
- **Children over 12 years to 18 years:** 2 tablets (whole or crushed) every day (130 mg)
- **Babies at birth to 1 month:** Tablets can be crushed and mixed in many liquids. To take the tablet in liquid solution, use dosing directions under in 24 hours. Do not take it more often. More KI will not help you. Too much KI may increase the chances of side effects.

#### HOW POTASSIUM IODIDE WORKS

Certain forms of iodine help your thyroid gland work right. Most people get the iodine they need from foods like iodized salt or fish. The thyroid can “store” or hold only a certain amount of iodine. Too much iodine breathed or swallowed may enter the thyroid gland and damage it. The damage would probably not show for years. If you take KI, it will block or reduce the chances that radioactive iodine will enter your thyroid gland.

### WHO SHOULD NOT TAKE POTASSIUM IODIDE

People should avoid KI if they are allergic to iodine, have dermatitis herpetiformis or hypocomplementemic vasculitis, or have nodular thyroid disease with heart disease, because these conditions may increase the chances of short-term use of KI to block the uptake of radioactive iodine by the thyroid gland. Because KI is a medicine, keep it out of the reach of children.

### SIDE EFFECTS

Short-term use of KI at the recommended dose is safe. You should not take this drug for longer than you know you need it. If you take KI, you may have some of the following side effects:

- Dry mouth
- Throat irritation
- Skin rashes such as hives
- Other allergic reactions

Get medical attention right away if you have trouble breathing, speaking or swallowing; wheezing; shortness of breath; or swelling of the mouth, tongue or throat.

### WHAT TO DO IF SIDE EFFECTS OCCUR

Stop taking KI and call a doctor if you have one or more of the following symptoms:

- Trouble breathing, wheezing, shortness of breath
- Swelling of the mouth, tongue or throat
- Skin rash such as hives
- Other allergic reactions

### HOW TO TAKE POTASSIUM IODIDE

#### Dosage Guide

<table>
<thead>
<tr>
<th>Child's Age</th>
<th>Dosage Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 1 month</td>
<td>2 teaspoons will give you a 16.25 mg dose</td>
</tr>
<tr>
<td>Over 3 to 12 years</td>
<td>8 teaspoons will give you a 65 mg dose</td>
</tr>
<tr>
<td>Over 12 to 18 years</td>
<td>2 tablets will give you a 130 mg dose</td>
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</tbody>
</table>

#### Tablets

1. Put 1 tablet into a small bowl
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. Mix the mixture gently with 8 ounces of chocolate milk, orange juice, flat soda, raspberry syrup, or infant formula.
4. The KI mixture will keep for 24 hours. Do not take it more often.

#### Making a Potassium Iodide Liquid

Follow these directions to make KI liquid:

1. Put 1 tablet into a small bowl
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. Mix the mixture gently with 8 ounces of chocolate milk, orange juice, flat soda, raspberry syrup, or infant formula.
4. The KI mixture will keep for 24 hours. Do not take it more often.

#### Precautions

If you take KI, it will block or reduce the chances that radioactive iodine will enter your thyroid gland. Because KI is a medicine, keep it out of the reach of children.