RADIBAN - potassium iodide tablet
United Douglas Pharm., Inc.

Active Ingredient (in each tablet) .... Potassium Iodide 130 mg.

Purpose --- Thyroid Blocking

Use --- Potassium iodide helps prevent radioactive iodine from getting into the thyroid gland during a nuclear radiation emergency. Use along with other emergency measures recommended by public officials.

Keep out of reach of children.

Radiban (Potassium iodide tablet, USP) is a thyroid blocking medicine that helps prevent radioactive iodine from getting into the thyroid gland during a nuclear radiation emergency. Use along with other emergency measures recommended by public officials. Radiban is to be used only in the case of a nuclear radiation emergency. It is not for everyday use. Because of the stability of potassium iodide, the shelf life for Radiban is 10 years.

Allergy Alert: Iodine may cause an allergic reaction with one or more of the following symptoms:

- Shortness of breath or wheezing
- Swelling
- Skin rash
- Trouble breathing, speaking, or swallowing
- Fever and joint pain

Do not use if you have:

- Ever had an allergic reaction to iodine
- Nodular thyroid disease with heart disease
- Hypocomplementemic vasculitis
- Dermatitis herpetiformis

Stop use and ask doctor if you have:

- Allergic reaction. Get medical help right away if you have trouble breathing, speaking, or swallowing; shortness of breath; wheezing; swelling of the mouth, tongue, or throat; or rash.
- Irregular heartbeat or chest pain. Get help right away.
- Swelling of the hands or feet, fever, or joint pain.

Directions

- Use only as directed by public officials in the event of a nuclear radiation emergency.
- Do not take more than 1 dose in 24 hours.
- Tablets can be whole or crushed and mixed with milk, water, orange juice, flat soda like cola, or raspberry syrup.

Dosage:

Adults over 18 years ..... 1 tablet (whole or crushed) daily (130 mg)

Children over 12 years to 18 years who weigh at least 150 pounds ..... 1 Tablet (whole or

crushed) daily (130 mg)

Children over 12 years to 18 years who weigh less than 150 pounds ..... 1/2 Tablet (whole or crushed) or 4 teaspoons of liquid mix daily (65 mg)

Children over 3 years to 12 years ..... 1/2 Tablet (whole or crushed) or 4 teaspoons of liquid mix daily (65 mg)

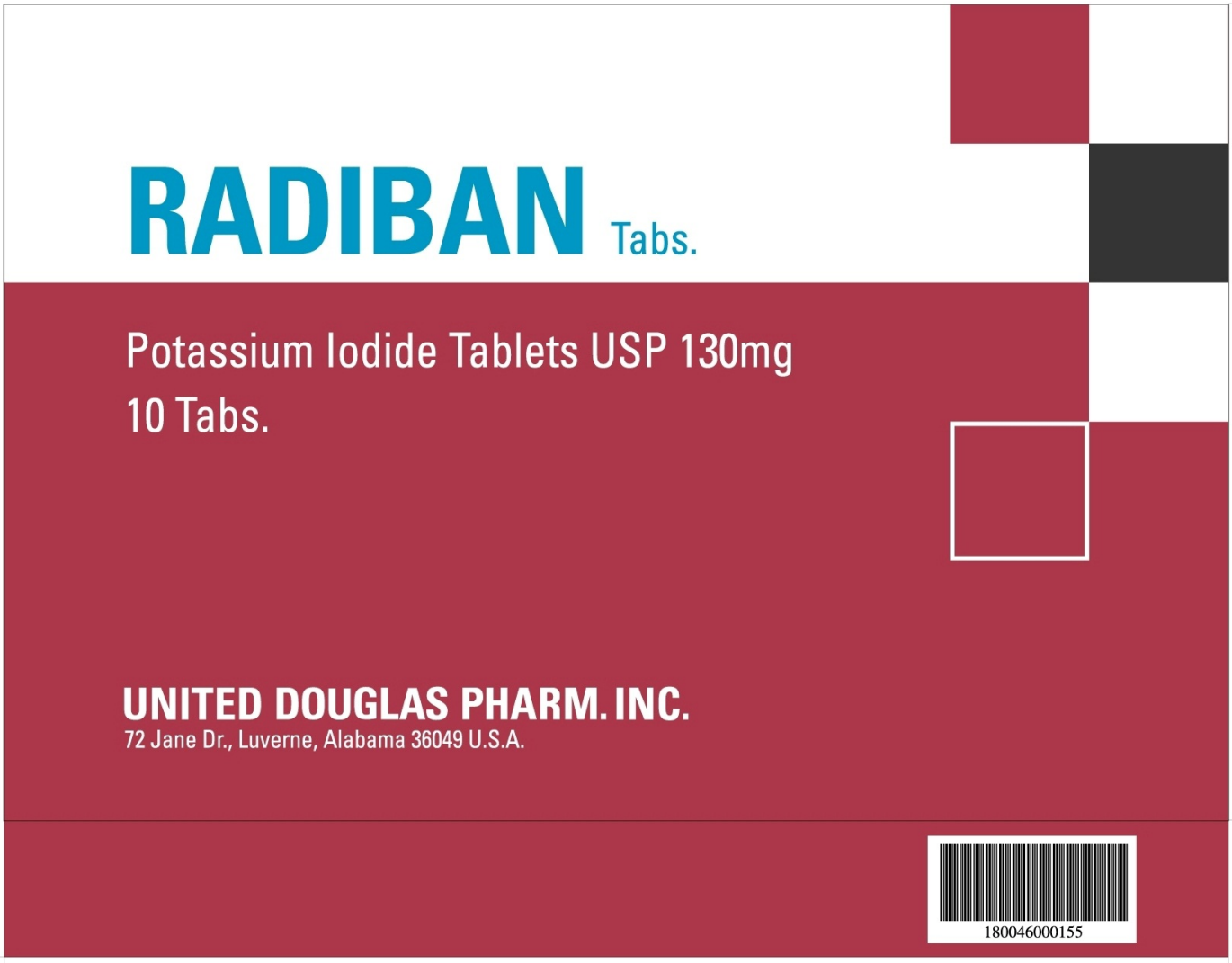
Children over 1 month to 3 years ..... 2 teaspoons of liquid mix daily (32.5 mg)

Infants at birth to 1 month ..... 1 teaspoon of liquid mix daily (16.25 mg)

The liquid mixture should be given to infants, young children, and any others who cannot swallow tablets; see consumer package insert on how to make a liquid mixture.

Inactive Ingredients: Microcrystalline cellulose, Lactose hydrate, Light Anhydrous Silicic Acid, Magnesium Stearate

Radiban Label Text



RADIBAN Tabs.

The liquid mixture should be given to infants, young children, and others who cannot swallow tablets; see consumer package insert on how to make a liquid mixture.

Active Ingredients(in each tablet) ***Purpose***

Potassium Iodide 130mg.....Thyroid blocking

Use helps prevent radioactive iodine from getting into the thyroid gland during a nuclear radiation emergency. Use along with other emergency measures recommended by public officials

Warnings

Allergy alert: Iodine may cause an allergic reaction with one or more of the following symtoms:

- shortness of breath or wheezing
- swelling
- skin rash
- trouble breathing speaking or swallowing
- fever and joint pain

Do not use: if you have

- ever had an allergic reaction to iodine
- nodular thyroid disease with heart disease
- hypocomplementemic vasculitis
- dermatitis herpetiformis

Stop use and ask a doctor if you have

- allergic reaction. Get medical help right away if you have trouble breathing, speaking or swallowing; shortness of breath; wheezing; swelling of the mouth, tongue or throat; or rash
- irregular heart or chest pain. Get medical help right away.
- swelling of the hands or feet, fever or joint pain

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- use only as directed by public officials in the event of a nuclear radiation emergency
- do not take more than 1 dose in 24 hours
- tablets can be whole or crushed and mixed in milk, baby formula, water, orange juice, flat soda like cola, or raspberry syrup,

Adults over 18 years	1 tablet (whole or crushed) daily (130 mg)
Children over 12 years to 18 years who weigh at least 150 pound	1 tablet (whole or crushed) daily (130 mg)
Children over 12 years to 18 years who weigh less than 150 pounds	1/2 tablet (whole or crushed) daily (65 mg)
Children over 3 years to 12 years	1/2 tablet (whole or crushed) daily (65 mg)
Children over 1 month to 3 years	32.5mg daily as directed in the consumer package insert
Babies at birth to 1 month	16.25mg daily as directed in the consumer package insert

If pregnant, breastfeeding, have a baby up to 1 month of age, or have thyroid disease(expect nodular thyroid disease with heart disease), take as directed above and contact a doctor as soon as possible.

Other information

- store at 20-25°C(68-77°F)
- keep dry and foil intact
- protect from light
- **do not throw away consumer package insert**

Question or comments? Call 1-334-335-4842

Inactive ingredients Microcrystalline cellulose, Lactose hydrate, Light Anhydrous Silicic Acid, Magnesium Stearate

UNITED DOUGLAS PHARM.INC.

72 Jane Dr., Luverne, Alabama 36049 U.S.A.

NDC:

Radiban Insert text

RADIBAN Tablets

(Potassium Iodide Tablets USP, 130 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 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 or light yellow, round, scored "UT" stamped on one side and "I" stamped the other side - tablet contains 130 mg of potassium iodide.

INDICATIONS

Radiban (Potassium iodide tablet, 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	1 tablet (whole or crushed) every day (130 mg)
Children over 12 years to 18 years who weigh at least 150 pounds	1 tablet (whole or crushed) every day (130 mg)
Children over 12 years to 18 years who weigh less than 150 pounds	1/2 tablet (whole or crushed) or 4 teaspoonfuls every day (65 mg)
Children over 3 years to 12 years	1/2 tablet (whole or crushed) or 4 teaspoonfuls every day (65 mg)
Children over 1 month to 3 years	2 teaspoonfuls every day (32.5 mg)
Babies at birth to 1 month	1 teaspoonful 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.

Making a Potassium Iodide Liquid Mixture:

1. Put one 130 mg KI tablet into a small bowl and grind it into a fine powder using the back of a metal teaspoon against the inside of the bowl. The powder should not have any large pieces.
2. Add 4 teaspoonfuls of water to the crushed KI powder in the bowl and mix until the KI powder is dissolved in the water.
3. Take the KI water mixture solution made in step 2 and mix it with 4 teaspoonfuls of low fat white or chocolate milk, orange juice, flat soda, raspberry syrup, or infant formula.
4. The KI liquid mixture will keep for up to 7 days in the refrigerator. It is recommended that the KI liquid mixtures be prepared weekly. Throw away unused portions.

The amount of KI (130 mg tablet) in the drink when mixed as described above is 16.25 mg per teaspoonful. The number of teaspoonfuls of the drink to give your child depends on your child's age as described in the following table:

Child's Age	Give your child this amount in teaspoonfuls
Over 12 to 18 years old who weigh less than 150 pounds	4 teaspoonfuls will give you a 65 mg dose
Over 3 to 12 years old	4 teaspoonfuls will give you a 65 mg dose
Over 1 month to 3 years old	2 teaspoonfuls will give you a 32.5 mg dose
Birth to 1 month	1 teaspoonful will give you a 16.25 mg dose

Note: This is the amount to give your child for one single dose in teaspoonfuls (not tablespoonfuls). You should give your child one dose each day as recommended by the public officials.
Pregnant or breastfeeding women or babies under 1 month of age: Take as directed above and call a doctor as soon as possible. Repeat dosing should be avoided. It is recommended that thyroid function be checked in babies less than 1 month of age that take KI. Women who are pregnant or breastfeeding should also be checked by a doctor if repeat dosing is necessary. Although these precautions should be taken, the benefits of short-term use of KI to block uptake of radioactive iodine by the thyroid gland far exceed its chances of side effects.

Patients with thyroid disease: If you have both a nodular thyroid condition such as multinodular goiter with heart disease, you should not take KI. Patients with other thyroid conditions may take KI as directed above, but call a doctor if you need to take KI for more than a few days.

WARNING

People who are allergic to iodine, have dermatitis herpetiformis or hypocomplementemic vasculitis, or have nodular thyroid disease with heart disease should not take KI. Keep out of the reach of children. In case of an allergic reaction (difficulty breathing, speaking or swallowing; wheezing; shortness of breath or swelling of the mouth or throat), call 911 or get medical care right away. In case of overdose, get medical help or call a Poison Control Center right away.

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.
In a nuclear radiation emergency, radioactive iodine may be released in the air. This material may be breathed or swallowed. It may enter the thyroid gland and damage it. The damage would probably not show itself for years. Children are most likely to have thyroid damage. 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 side effects to iodine.

HOW AND WHEN TO TAKE POTASSIUM IODIDE

KI should be taken as soon as possible after public officials tell you. If you are told to repeat the dose, you should take the second dose 24 hours after the first dose. Do not take it sooner. More KI will not help you because the thyroid can "hold" only certain amounts of iodine. Taking more than 1 dose per day will increase the chances of side effects. The public officials will tell you how many days to take KI. You should take KI until the chances of major exposure to radioactive iodine by breathing or swallowing stops.

SIDE EFFECTS

Short-term use of KI at the recommended dose is safe. You should not take this drug for longer than you are told. 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
- skin rashes such as hives
- 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
- wheezing or shortness of breath

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. Taking iodide, in rare cases, 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 irregular heart beat and chest pain. Patients with thyroid disease are more likely to get these side effects.
Babies under 1 month of age are more likely to get an underactive thyroid gland (hypothyroidism).

WHAT TO DO IF SIDE EFFECTS OCCUR

Stop taking KI and call a doctor if you have one or more of the following symptoms:
- swelling of the face, hands or feet
- fever and joint pain
- skin rash

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

SHELF LIFE

Ten(10) years from manufacturing date.

HOW SUPPLIED

Potassium iodide tablets, USP. Packages of 10 tablets. Each white, round, tablet contains 130 mg potassium iodide. Store at 20-25°C(68-77°F). Keep dry and foil intact.
UNITED DOUGLAS PHARM.INC. 72 Jane Dr., Luverne, Alabama 36049 U.S.A.

UNITED DOUGLAS PHARM. INC.

RADIBAN

potassium iodide tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65697-513
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Iodide (UNII: 1C4QK22F9J) (Iodine - UNII:9679TC07X4)	Potassium Iodide	130 mg

Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Magnesium Stearate (UNII: 70097M6I30)	

Product Characteristics

Color	yellow (Very light yellow - almost white tablet)	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	UT;I
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65697-513-11	10 in 1 BOX		
1	NDC:65697-513-01	1 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		12/20/2011	

Labeler - United Douglas Pharm., Inc. (001444350)

Registrant - United Douglas Pharm., Inc. (001444350)

Establishment

Name	Address	ID/FEI	Business Operations
United Douglas Pharm., Inc.		001444350	pack, label

Establishment

Name	Address	ID/FEI	Business Operations
Korea United Pharm Inc.		688016534	manufacture