THYROSAFE- potassium iodide tablet
Recipharm AB (publ)

Drug Facts

Active Ingredient (in each tablet)

Potassium Iodide 65 mg

Purpose

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 1 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 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 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. **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.**

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

- **if pregnant, breastfeeding, have a baby up to 1 month of age, or have thyroid disease (except 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**

Inactive ingredients

lactose, magnesium stearate, microcrystalline cellulose

Questions or comments?

call toll free 1-866-849-7672

Principal Display Panel - 65 mg Carton Label

NDC-66983-350-20

ThyroSafe®

Potassium Iodide Tablets, USP, 65 mg

Thyroid blocking in a radiation emergency only

20 tablets, 65 milligrams each

Recipharm

THYROSAFE

potassium iodide tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66983-350

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Iodide (UNII: 1C4QK22F9J) (Iodide Ion - UNII:09G4I6V86Q)	Potassium Iodide	65 mg

Inactive Ingredients

Ingredient Name	Strength
Lactose, Unspecified form (UNII: J2B2A4N98G)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Magnesium Stearate (UNII: 70097M6I30)	

Product Characteristics

Color	white (white)	**Score**	4 pieces
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66983-350-20	160 in 1 CARTON	09/30/2002	
1		20 in 1 BOX		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076350	09/30/2002	

Labeler - Recipharm AB (publ) (508619434)

Establishment

Name	Address	ID/FEI	Business Operations
Recipharm Fontaine		260428962	MANUFACTURE(66983-350)

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