

R & R REGISTRATIONS

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San Diego, CA 92196-2069TO: Ms. Cecilia Parist (301) 594-0183
Food and Drug Administration

FROM: Ronald G. Leonardi, Ph. D.

DATE: July 19, 2001

Number of pages (including this one): FIVE (5)**COMMENTS****RE: Potassium Iodide Recip 65mg – Citizen's Petition - Labels****Dear Ms. Parist:**

Reference is made to Citizen's Petition request to allow ANDA submission of Potassium Iodide dated October 19, 2000. Further reference is made to your telephone call of July 16, 2001 requesting revised copies of proposed product labeling for Potassium Iodide Recip to mimic the product labeling of the innovator (ANBEX) product, since the draft guidance has not yet been implemented. Attached are the copies of proposed product labeling for Potassium Iodide Recip.

Please contact our office should you need further information.

Sincerely,


Dr. Leonardi**Attachments**

- (1) Potassium Iodide Recip Product Label
- (2) Potassium Iodide Recip Product Labeling

00P-1574

SUP1

Potassium Iodide Recip 65 mg, tablets

(Potassium Iodide Tablets, U.S.P.)

(KI)

Take potassium iodide only when public health officials tell you. In a radiation emergency, radioactive iodine could be released into the air. Potassium Iodide (a form of iodine) can help protect you. If you are told to take this medicine, take it one time every 24 hours. Do not take it more often. More will not help you and may increase the risk of side effects. Do not take this drug if you know you are allergic to iodine (see side effects below).

Indications

Thyroid blocking in a radiation emergency only

Directions for use

Use only as directed by state or local public health authorities in the event of a radiation emergency.

Dose

Adults and children 1 Year of Age and Older: Two (2) tablets once a day. Crush for small children.

Babies Under 1 year of Age: One tablet once a day. Crush if needed.

Dosage: Take daily (every 24 hour) for 10 days unless directed otherwise, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exist as directed by state or local public health authorities.

Warning

Potassium iodide should not be used by people allergic to iodide. Keep out of the reach of children. In case of overdose or allergic reaction, contact a physician or public health authority.

Description

Each white, round, cross-scored Potassium Iodide tablet contains 65 mg of potassium iodide.

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 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 potassium iodide, it will fill up your thyroid gland. This reduces the chance that harmful radioactive iodine will enter the thyroid gland.

Who should not take potassium iodide

The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or anti-thyroid drug). Pregnant and nursing women and babies and children may also take this drug.

How and when to take potassium iodide

Potassium iodide should be taken as soon as possible after public health officials tell you. You should take one dose every 24 hours. More will not help you because the thyroid can "hold" only limited amounts of iodine. Larger doses will increase the risk of side effects. You should take potassium iodide until the risk of significant exposure to radioiodines by either inhalation or ingestion no longer exist. The public health officials will tell you.

Side effects

Usually, side effects of potassium iodide happen when people take higher doses for a long time. You should be careful not to take more than the recommended dose or take it for longer than you are told. Side effects are unlikely because of the low dose and the short time you will be taking the drug.

Possible side effects include skin rashes, swelling of the salivary glands, and "iodism" (metallic taste, burning mouth and throat, sore teeth and gums, symptoms of a head cold, and sometimes stomach upset and diarrhea).

A few people have an allergic reaction with more serious symptoms. These could be fever and joint pains, or swelling of parts of the face and body and at times severe shortness of breath requiring immediate medical attention.

Taking iodide may rarely cause overactivity of the thyroid gland, underactivity of the thyroid gland, or enlargement of the thyroid gland (goiter).

What to do if side effects occur

If the side effects are severe or if you have an allergic reaction, stop taking potassium iodide. Then, if possible, call a doctor or public health authority for instructions.

How supplied

Potassium Iodide Recip tablets. Packages of 10 tablets . (xxxx). Each white, round, cross-scored tablet contains 65 mg Potassium iodide.

Store at controlled room temperature between 15° and 30°C (59° and 86°F).

Potassium Iodide Recip 65 mg tablets
Text on carton. DRAFT

10 tablets

Potassium Iodide Recip 65 mg

Potassium Iodide Tablets, U.S.P.

Keep out of reach of children

**Indication: Thyroid blocking in
a radiation emergency only**

Batch No
Exp. date

10 tablets

Potassium Iodide Recip 65 mg

**Take only in the presence of radioactive iodine
(nuclear fallout).**

Use as directed in the leaflet.