Patient Information Sheet for RadBlock™
(Potassium Iodide Tablets USP, 65 mg)

Take RadBlock™ or give to children only when public health officials advise you. In a radiation emergency, radioactive iodine could be released into the air. RadBlock™ protects the thyroid gland from radioactive iodine. Children up to 18 years of age are most at risk. It is important that you follow instructions carefully when administering RadBlock™ to children.

If you are told to take this medicine, take it one time every 24 hours. Health care authorities will advise you for how long you should take RadBlock™. Do not take it more often or at higher doses. More RadBlock™ will not help you and may increase the risk of side effects. If you are pregnant or nursing, do not take more than one dose of RadBlock™. Do not take this drug if you are allergic to iodine.

INDICATIONS
Radblock™ is 90% if potassium iodide is taken 12 hours, and 70% if taken 24 hours prior to radiation such as evacuation, shelter and agricultural and food measures to limit exposure.

The protective effect is negligible if potassium iodide is taken 1 and 3 hours after exposure. The protective effect is 97% if administered 30 minutes before exposure. No serious side effects are reported. (Source: WHO/SDE/PHE/99.6)

DIRECTIONS FOR USE
Follow these instructions exactly unless advised otherwise by public health authorities in the event of a radiation emergency.

Dose:

Adults and children 18 years and older
Take 2 tablets daily, whole or crushed (total dose 130 mg)

Children 3 years to 18 years*
Take 1 tablet daily, whole or crushed (total dose 65 mg)

Children 1 month to 3 years
Take ½ tablet daily, crushed in food or fluids (total dose 32.5 mg)

Children under 1 month
Take ½ tablet dissolved in formula (total dose 16 mg)

Pregnant or Breastfeeding women
Take 2 tablets daily, whole or crushed (total dose 130 mg)
Take only one dose. Do not repeat.

* Adolescents approaching adult size (70 kg) should take the full adult dose (130 mg)

Take the tablet or portion of the tablet with a full glass of liquid (250 mL) to help reduce stomach upset.

Description
Each light yellow, round, scored RadBlock™ tablet contains 65 mg of Potassium Iodide. These tablets have a coating that masks the bitter taste of potassium iodide, when the tablets are swallowed whole.

Non-medicinal ingredients: Hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol 400, polysorbate 80, FD&C Yellow #5, FD&C Blue #2, FD&C Yellow #6.

WARNING
Patients with thyroid disease who have a nodular thyroid condition, such as multinodular goiter, in addition to heart disease, should not take potassium iodide.

Patients with other thyroid conditions, such as Grave's disease, autoimmune thyroiditis or multinodular goiter without heart disease, should take Radblock™ as directed above. Please contact your doctor if you have to take this product for longer than 3 days.

People who are allergic to iodine, have dermatitis herpetiformis or hypocomplementemic vasculitis, or have nodular thyroid disease in addition to heart disease should not take Radblock™. In case of an allergic reaction (swelling of arms, face, legs, lips, tongue, difficulty in breathing, speaking, or swallowing; shortness of breath and/or appearance of severe rash), contact a doctor or public health authority immediately.

In case of overdose, get medical help or call a Poison Control Centre immediately.

Thyroid function must be checked in babies less than one month of age who are given Radblock™.

Women who are pregnant or nursing should also be checked by a doctor if repeat dosing is necessary.

Those with kidney disease, take as directed above and contact a health care provider as soon as possible.

Keep out of reach of children.

HOW RadBlock™ 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 (such as in a severe nuclear power plant accident or a nuclear bomb explosion), radioactive iodine may be released into the air and can result in dangerous radioiodine risks in areas up to 100s of kilometers from the release or burst point. This material may be breathed or swallowed. It may then enter the thyroid gland and damage it. The damage would probably not show itself for years but can result in diseases like thyroid cancer. Children are most likely to have thyroid damage. (Sources: WHO/SDE/PHE/99.6 and The Effects of Nuclear Weapons, US Department of Defense, 1977)

If you take Radblock™, it will fill up your thyroid gland with stable (non-radioactive) iodine and block or reduce the chance that dangerous radioactive iodine will enter your thyroid gland.

SIDE EFFECTS
Short-term use of Radblock™ at the recommended dose can have some side effects. For example, in Poland, single doses of stable iodine were given to 10 million children to protect them from radioactive iodine exposure in the aftermath of the Chernobyl nuclear power plant disaster. No serious side effects were seen with these children, although minor rashes and gastrointestinal effects were reported. (Source: WHO/SDE/PHE/99.6)

You should not take this drug for longer than told.

Possible side effects include: increase in salivation, burning in mouth and throat, swelling of the salivary glands, 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 attention right away if you have trouble breathing, speaking or swallowing; wheezing, shortness of breath, or swallowing of the mouth, tongue or throat

Taking Radblock™, in rare cases, may cause over-activity of the thyroid gland, under-activity 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 undersh pacing thyroid (hypothyroidism) when given Radblock™.

DRUG INTERACTIONS
If you are taking antithyroid drugs, lithium, captopril, enalapril, lisinopril, or potassium sparing diuretics, take Radblock™ as directed above and contact a doctor as soon as possible, as you may need to undergo certain laboratory tests regarding function of your thyroid or the levels of potassium in your blood.

WHAT TO DO IF SIDE EFFECTS OCCUR
Stop taking Radblock™ 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 Radblock™ 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
Radblock™ tablets contain 65 mg Potassium Iodide. Bottles of 200, 56 and 28 tablets

Store at 15 - 30°C. Protect from light and moisture.

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