

PACKAGE LEAFLET: INFORMATION FOR THE USER



ThySat® 65 mg tablets
Potassium iodide

STOP



ThySat should **only** be taken when there is a risk of exposure to nuclear radiation. ThySat contains potassium iodide which, when taken at the correct dosage, saturates your thyroid gland with iodine and blocks it from absorbing radioactive iodine helping to prevent thyroid cancer.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ThySat is and what it is used for
2. What you need to know before you take ThySat
3. How to take ThySat
4. Possible side effects
5. How to store ThySat
6. Contents of the pack and other information

1. What ThySat is and what it is used for

Potassium iodide is a thyroid blocking agent used to prevent harm caused by radioactive iodine.

When taken by someone exposed to radioactive iodine, potassium iodide may prevent damage to the thyroid gland by saturating it with non-radioactive iodine blocking the uptake of radioactive iodine from contaminated air, water, milk and other sources.

2. What you need to know before you take ThySat

Do not take ThySat if you:

- are, or think you may be, allergic to potassium iodide or any of the other ingredients of this medicine (listed in section 6).

If you are allergic to potassium iodide or any of the ingredients listed in section 6 consult your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking ThySat if you:

- are being treated for a thyroid problem
- suffer from dermatitis herpetiformis (a skin disease)
- suffer from hypocomplementaemic vasculitis (a disease causing inflammation of the blood vessels)
- have problems with your kidneys
- have problems or you are being treated for problems with your adrenal glands
- are suffering from dehydration or cramp due to extreme heat.

If you are uncertain about any of the above you may want to ask your doctor or pharmacist for advice before taking this medicine.

Other medicines and ThySat

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription. In particular, you may not be able to use the following medicines whilst you are taking ThySat:

- some drugs used to treat heart problems or high blood pressure, such as quinidine or ACE inhibitors (e.g. captopril or enalapril).
- diuretics ("water tablets") which may affect the level of potassium in the blood such as amiloride or triamterene.
- other drugs that may affect the thyroid, including lithium (used in the treatment of mania, bipolar disorder, and recurrent depression) and amiodarone (used in the treatment of abnormal heart rhythms).

Pregnancy and breast-feeding

Iodine prophylaxis should be undertaken in case of a nuclear accident or when radioactive iodine is released, in all people involved including pregnant and breast-feeding women located in the endangered area. If you are pregnant or breast-feeding, this medicine can be taken over a short period of time. You should continue to breast feed if you are taking this medicine.

Driving and using machines

ThySat has no or negligible influence on the ability to drive and use machines.

3. How to take ThySat

The recommended dose of potassium iodide is listed in the table below. You should check with your doctor or pharmacist if you are not sure about the dose you require.

Age	Dose	Quantity of potassium iodide
Neonates Babies up to 1 month	Quarter of a tablet	16 mg
Children from 1 month to 3 years	Half a tablet	32 mg
Children from 3 to 12 years	1 tablet	65 mg
Adults, elderly and children over 12 years	2 tablets	130 mg

The tablets should be taken as a single dose as soon as you are advised to do so. Delay may result in reduced effectiveness.

35 mm

2275

Pharmacode



Pharmacode
2275

35 mm



For children the dose may be crushed and mixed with milk, water or juice before administration.

In case of prolonged exposure, repeat dosing may be necessary although if you are pregnant or breastfeeding you should normally not take more than two doses. You must also get medical advice since potassium iodide may affect the thyroid of your child and tests from your doctor can establish and correct this. Babies up to a month old should only receive one dose and should have their thyroid function assessed by their doctor.

After taking potassium iodide babies under the age of 3 months should be taken to see their doctor as soon as possible so that their thyroid function can be closely monitored.

Women in the last 3 months of their pregnancy should inform their doctor and other healthcare professionals that they have taken potassium iodide, as a blood sample from the umbilical cord should be taken to measure the baby's thyroid function.

If you take more ThySat than you should

Taking higher doses of potassium iodide does not increase the protective effect. If you (or someone else) swallow lots of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, contact your nearest hospital casualty department or a doctor immediately.

4. Possible side effects

ThySat is taken by the majority of patients without any problems. However, like all medicines, this medicine can cause side effects, although not everybody gets them. These may include:

- hypersensitivity reactions such as a rash, swollen salivary glands, headache, wheezing or coughing.
- an overactive thyroid gland (characterised by weight loss, increased appetite, intolerance to heat and increased sweating).
- an enlarged thyroid gland with or without the development of myxoedema (a condition in which there is a thickening of the skin and body tissues, most notably the face).
- stomach upsets, feeling sick, disturbances of taste including a metallic taste in the mouth.

Continued use may lead to depression, nervousness, insomnia or impotence.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. In the event of a nuclear emergency, there are other protective actions you can take against radiation damage. Emergency assistance should be sought in order to avoid further dangerous contamination. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ThySat

Do not store above 25°C.

Keep the blister in the outer carton in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measure will help protect the environment.

6. Contents of the pack and other information

What ThySat contains

- The active substance is 65 mg potassium iodide which is equivalent to 50 mg of iodine.
- The other ingredients are microcrystalline cellulose, talc and colloidal anhydrous silica.

What ThySat looks like and contents of the pack

The tablets are white to yellowish slightly marbled round tablets with a smooth surface without any defects, cross-scored for ease of breaking.

2, 4, 10 or 100 tablets in one pack

Not all pack sizes may be marketed.

Marketing Authorisation Holder

hameln pharma ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG, UK

Manufacturer

hameln rds s.r.o.
Horná 36
900 01 Modra, Slovak Republic

Saneca Pharmaceuticals a.s.
Nitrianska 100
920 27 Hlohovec, Slovak Republic

This medicinal product is authorised in the Member States of the EEA under the following names:

Poland	Jodek potasu HEMO MEDIKA, tabletki
Slovak Republic	JODID DRASELNÝ 65 hameln, tablety
United Kingdom (Northern Ireland)	ThySat® 65 mg tablets

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35 mm



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