Package leaflet: Information for the patient

MBROTIR L 65 mg tablets

Potassium iodide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 MBROTIR L is and what it is used for

What MBROTIR L is
MBROTIR L contains the active substance ‘potassium iodide’. Potassium iodide is a chemical compound, medication, and dietary supplement.
Potassium iodide is a thyroid blocking agent used to prevent harm caused by radioactive iodine.

What MBROTIR L is used for
MBROTIR L is used in cases of nuclear accidents or nuclear reactor accidents to prevent the uptake of radioactive iodine by the thyroid.

In the event of nuclear reactor accidents, there may be an emission of radioactive iodine. In case of contamination, the radioactive iodine is taken up by the thyroid. The uptake of radioactive iodine by the thyroid is prevented by the intake of non-radioactive iodine (e.g. in the form of potassium iodide) before or during the contamination.

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

2. What you need to know before you take MBROTIR L

You must read the package leaflet of all medicinal products to be taken in combination with MBROTIR L before starting treatment with MBROTIR L.

Do not take MBROTIR L:
- if you are allergic to potassium iodide or any of the other ingredients of this medicine listed in section 6. If you think you may be allergic, ask your doctor for advice,
- if you have an autoimmune disease involving itching and blisters of your skin (dermatitis herpetiformis van Dühring),
- if you have an overactive thyroid producing too much of thyroid hormones (hyperthyreosis),
- if you have a certain disorder of your blood vessel walls (hypocomplementaemic vasculitis).

If any of these apply to you, do not take MBROTIR L. Talk to your doctor if you are not sure.

Warnings and precautions
Talk to your doctor or pharmacist before taking MBROTIR L if:
- you have a malign tumor in your thyroid or if your doctor assumes that you have one,
- you have a narrowing of your wind-pipe (causing respiratory problems). The use of MBROTIR L may worsen this condition,
- you are being treated or were treated in the past for a thyroid problem,
- you have a specific problem with your thyroid called thyroid autonomy and are not being treated for it,
- you have problems with your kidneys.
- you have problems or are being treated for problems with your adrenal glands,
- you are suffering from dehydration or cramp due to extreme heat,
- you are taking any of the medicines listed in section "Other medicines and MBROTIR L".

If any of the above apply to you, tell your doctor before starting treatment.

Children
Babies until a few weeks of age should be taken to the doctor as soon as possible after being given MBROTIR L so that their thyroid function can be closely monitored.

Other medicines and MBROTIR L
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because MBROTIR L can affect the way some other medicines work. Also, some other medicines can affect the way MBROTIR L works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- medicines inhibiting the thyroid function; when taken concomitantly with MBROTIR L you should be closely monitored by a doctor,
- captopril or enalapril; these medicines may cause an increased potassium level in your blood,
- quinidine; the effect of quinidine on the heart is increased by MBROTIR L,

- potassium-sparing diuretics ("water tablets") such as amiloride or triamterene; those medicines may cause an increased potassium level in your blood.

The use of MBROTIR L may influence radioiodine therapy and the results of thyroid tests.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnant women should not take more than one dose of 2 tablets. If MBROTIR L is taken in late pregnancy, it is recommended to check the thyroid function of the newborn.

Breast-feeding women should not take more than one dose of 2 tablets.

Iodide is excreted into breast milk, but the amount is not enough for the complete protection of the baby. Therefore, iodide tablets have to be given to the baby as well.

(See section 3, "How to take MBROTIR L".)

Driving and using machines
MBROTIR L has no influence on the ability to drive or use machines.

3. How to take MBROTIR L

MBROTIR L tablets may only be taken in cases of nuclear accidents and if announced by the respective authority, e.g. via radio or television.
Do not take the tablets on your own account.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For best possible protection it is necessary to take the tablets as soon as possible (preferably within two hours) after the announcement that radioactive iodine has been released.
However, it is still useful to take the tablets up to 8 hours after the exposure to radioactive iodine.

The tablets swallowed whole. For sucklings, the tablets can be pulverized or dispersed in water, syrup or similar liquids. It may take up to 6 minutes until the tablets are fully dispersed. Make sure that the tablets are fully dispersed before you give them to your child.

The recommended dose is:

Adults and children 12 years or older:	2 tablets
Children aged 3 to 12 years:	1 tablet
Children aged 1 month to 3 years:	½ tablet
Newborns and babies younger than 1 month:	¼ tablet
Pregnant women (all ages):	2 tablets

	With this dose your unborn child is protected as well.
Breast-feeding women (all ages):	2 tablets

Newborns, pregnant and breast-feeding women and adults older than 60 years should not take more than one single dose.

The single intake of the above-mentioned doses protects against the possible uptake of radioactive iodine.

If the release of radioactive iodine continues (over 24 hours), with repeated exposure, intake of contaminated food or drinking water and if evacuation is not possible, a repeated administration may be necessary.

The tablet can be divided into equal doses.

If you take more MBROTIR L than you should
Taking more of MBROTIR L than described above does not increase the protective effect. If you have taken too much of MBROTIR L, iodine poisoning may occur with severe side effects such as respiratory and heart problems.

If you have taken too much of MBROTIR L, contact your doctor immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare (may affect up to 1 in 1 000 people):
- Temporary skin rash

Not known (frequency cannot be estimated from the available data):
- Hypersensitivity reactions such as swollen salivary glands, headache, wheezing or coughing, and stomach upset
- Iodine-induced autoimmune disorders (Grave's disease, Hashimoto's disease), harmful nodular goitre and iodine-induced temporary thyroid hyperfunction or hypofunction
- Overactive thyroid gland (characterised by weight loss, increased appetite, intolerance to heat and increased sweating), inflammation of the thyroid, 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)
- Depression, nervousness, impotence, and sleeplessness (after continued administration)
- Sialadenitis (an inflammation of the saliva gland), gastrointestinal disturbances

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store MBROTIR L

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 carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in the original package in order to protect from light and moisture.

Do not use this medicine if you notice any damage or signs of tampering to the pack.

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

6. Contents of the pack and other information

What MBROTIR L contains

- The active substance is potassium iodide. Each tablet contains 65 mg of potassium iodide equivalent to 50 mg iodine.
- The other ingredients are: Hydroxypropyl methylcellulose 4000 mPa, microcrystalline cellulose, croscarmellose sodium, trisodium citrate 2-hydrate and magnesium stearate.

What MBROTIR L looks like and contents of the pack

The tablets are white to yellowish in colour, round tablets with a smooth surface without any defects.

Plastic bottles containing 2, 6, 10, 20 or 100 tablets in cartoon box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
LEKLI sh.p.k
Rr.Reshit Petrela
Nd. 7/143, 1057 Tirana,
Albania

Manufacturer

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Rr.Reshit Petrela
Nd. 7/143, 1057 Tirana,
Albania

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