Package leaflet: Information for the user®

IODOMARIN® 200 µg tablets

potassium iodide

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 doctor or 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

1. What IODOMARIN® is and what it is used for

IODOMARIN® is used for:
- - Preventing iodine deficiency (e.g. preventing goitre in iodine-deficiency areas and after removal of iodine-deficiency goitre)
- - Treating goitre in newborns, infants, children, adolescents and young adults

2 What you need to know before you use IODOMARIN®

Do not use IODOMARIN®

- If you are allergic to potassium iodide or any of the other ingredients of this medicine (listed in section 6)
- In a manifestly overactive thyroid (with complaints)
- In a latently overactive thyroid (without complaints) in a dosage of over 150 µg iodine/day
- In benign, hormone-forming growth or uncontrolled hormone-forming areas of the thyroid in a dosage of 300-1,000 µg iodine/day (except in treatment before surgery).

Warnings and precautions

Talk to your doctor or pharmacist before using IODOMARIN®

Other medicines and IODOMARIN®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Iodine deficiency increases the response to a therapy of an overactive thyroid with medicines, whereas excessive iodine decreases it. Every avoidable administration of iodine before and during treatment of an overactive thyroid should therefore not be carried out.

Substances that are introduced into the thyroid via the same mechanism as iodide (e.g. perchlorate), as well as substances that are not transported themselves (like thiocyanate at concentrations over 5 mg/dl), inhibit the iodine uptake of the thyroid.
Iodine uptake and iodine turnover of the thyroid are stimulated by the body's own and externally supplied TSH (thyroid-stimulating hormone).

Treatment at the same time with high iodine doses, which inhibit the hormone formation of the thyroid, and lithium salts (medicines mainly used to treat psychiatric disorders) may favour the development of goitre and an underactive thyroid.

High doses of potassium iodide in association with potassium-sparing, urine output-increasing medicines may lead to raised potassium levels in the blood.

Pregnancy, **breast-feeding and fertility**

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

An increased iodine requirement exists in pregnancy and the breast-feeding period, meaning that adequate iodine intake is particularly important. However, iodine and iodine-containing preparations should only be taken with benefit/risk evaluation and only at the explicit direction of the doctor.

Driving and using machines

No special precautions are required.

IODOMARIN® contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use IODOMARIN®

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.

The recommended dose is:

Goitre prevention in iodine deficiency
Newborns, infants and children:
Up to ½ a IODOMARIN® (equivalent to up to 100 µg iodine) once daily

Adolescents and adults:
½ - 1 IODOMARIN® tablet (equivalent to 100 - 200 µg iodine) once daily

Pregnancy and breast-feeding:
1 IODOMARIN® tablet (equivalent to 200 µg iodine) once daily

Prevention of new goitre growth after completion of a treatment with medicines or surgery of iodine-deficiency goitre

½ - 1 IODOMARIN® tablet (equivalent to 100 - 200 µg iodine) once daily

Treatment of iodine-deficiency goitre

Newborns, infants, children and adolescents:
½ - 1 <trade name>® tablet (equivalent to 100 - 200 µg iodine) once daily

Young adults:
1½ to 2½ <trade name>® tablets (equivalent to 300 - 500 µg iodine) once daily are recommended.

Method of use
Take IODOMARIN® after a meal with sufficient liquid (e.g. a glass of water).

Length of use
IODOMARIN® must generally be administered preventatively over a period of years, and not uncommonly for life.

2 - 4 weeks is usually adequate for treating goitre in newborns and infants; 6 - 12 months or more is usually required in children, adolescents and adults.

The tablet can be divided into equal doses.

If you take more IODOMARIN® than you should

Speak to a doctor straight away. They will decide about any measures that might be required.

If you forget to take IODOMARIN®

Do not take a double dose to make up for a forgotten dose.

If you stop taking IODOMARIN®

If you interrupt or prematurely end taking IODOMARIN®, for example due to a side effect, please speak to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Undesirable effects are not expected when iodide is used preventatively in every age range, as well as when used therapeutically in newborns, infants, children and adolescents. However, in the presence of large uncontrolled hormone-forming areas in the thyroid and daily iodine administration of more than 150 µg, an overactive thyroid becoming manifest cannot be ruled out completely.

Very rare (in less than 1 in 10,000 people)
Immune system
Hypersensitivity reactions, for example iodine-induced rhinitis, skin reactions (iododerma bullosum or tuberosum, exfoliative dermatitis), swelling of the skin or mucous membranes (angioneurotic oedema), fever, acne and salivary gland swelling.

Hormone system
When used for the therapy of goitre in adults (dosage of over 300 to not more than 1,000 µg iodine), an iodine-induced overactive thyroid may result. In the majority of cases, the prerequisite for this is uncontrolled hormone-forming areas in the thyroid. Elderly patients with long-standing goitre are mainly at risk.

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 listed in AppendixV. By reporting side effects you can also provide more information on the safety of this medicine.

5. How to store IODOMARIN®

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

This medicinal product does not require any special storage conditions.

Do not throw away 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 IODOMARIN® contains

The active substance is potassium iodide.
Each tablet contains 262 µg potassium iodide (equivalent to 200 µg iodide).

The other ingredients are:
Lactose monohydrate, light magnesium carbonate, gelatin, sodium starch glycolate (type A), colloidal anhydrous silica, magnesium stearate.

What IODOMARIN® looks like and contents of the pack

White or almost white tablets with biplanar surfaces, bevelled edges and break-mark on one side.

IODOMARIN® is available in packages with 25, 50 or 100 tablets (blister).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in November 2017.

Klicken Sie hier, um Text einzugeben.