Йодомарин (R)





Oral iodine supplementation with IODOMARIN®

Information for patients

Dear Reader

Iodine deficiency or goitre is something you might have heard about already. These conditions can occur if your body doesn't get enough iodine from your food. One way to prevent iodine deficiency and preserve your health is to use iodised salt at home or to eat foods rich in iodine. But this becomes difficult if you have to follow a special diet or have an increased need for iodine.

In this brochure we will provide information about importance and necessity of prevention or treatment, the consequences of iodine deficiency and who might be affected or in danger. Furthermore we will give you detailed information about oral supplementation to prevent iodine deficiency.

Thank you for your interest

Your Berlin-Chemie-Team

Йодомарин (Ranus йодид (R

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Йодомарин Калия йодид ®

What is iodine?

Iodine is an essential mineral nutrient and a trace element. A "trace element" is one that is needed by the body in minute quantities while "essential" means that the

body needs such a mineral but cannot produce it by itself. So it is important for your health to take sufficient iodine with food.

Iodine is needed in our bodies for normal thyroid gland functions. 70 to 80 percent of ingested iodine is concentrated in the thyroid gland – a classical endocrine gland. It is used for the synthesis of two important iodine containing thyroid hormones which are important for energy yielding metabolic and physiological processes and so for your health.



What are thyroid hormones for?

Thyroid hormones have distinct functions in the body during different growth phases. During pregnancy and in early years these hormones regulate the growth and development of organs and they are needed for proper growth and physical and mental development. Thyroid hormones also play a vital role in adolescents and are also involved in a variety of adult body functions being responsible for:

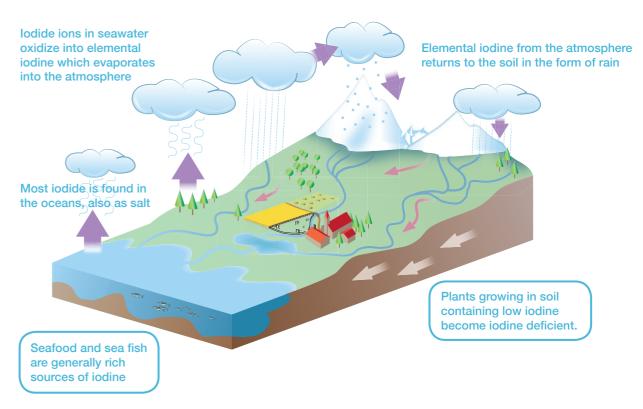
- Activation of the nervous system leading to higher attention levels and quicker reflexes
- Acceleration of the heart beat and increase in heart contraction
- Decrease of resistance in peripheral blood vessels
- Increase in the basic metabolic rate
- Increase in body temperature

The production of thyroid hormones in the thyroid gland is regulated via the brain by release of the thyroid-stimulation-hormone (TSH).

The iodine cycle

In nature most iodine is found in the oceans as iodide ions and compounded with other elements as salts. The iodide ions in salty seawater oxidize into elemental iodine.

This is the reason that sea fish and sea foods are generally good sources of iodine. Being volatile, it evaporates into the atmosphere above the oceans. Its good water solubility means that the iodine concentration in water droplets is very high when returned to the soil in the form of rain. As a result, growing plants easily accumulate the iodine. When these plants are eaten by animals they form a source of iodine for them. Hence good natural sources of iodine other than fish and seafood are cereal grains, meat, eggs and milk.



The natural iodine cycle

But this iodine cycle and the amount of iodine in it may differ and can cause a lack of iodine in food. Furthermore regions far from the ocean tend to lose iodine from the soil continuously and so the food and livestock in these regions are also deficient in iodine.



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Iodine deficiency

How much daily iodine you need depends on your age and certain conditions. The United Nations International Children's Fund (UNICEF), the International Council

for Control of Iodine Deficiency Disorders (ICCIDD) and the World Health Organization (WHO) recommend the following amounts:

Age group	Daily recommended iodine intake (μg)
0-59 months	90
6-12 years	120
Above 12 years, including adults	150
Pregnant women or breastfeeding mothers	250

Why there is a lack of iodine in food

As iodine is unevenly distributed in the environment and most of it is found in the oceans, the soil and groundwater in regions far from the sea often becomes iodine deficient. Older exposed soil surfaces in particular are more likely to have iodine leached away by erosion. Major mountain ranges like the Himalayas, the Andes, the Alps and flooded river valleys such as the Ganges are among the most

severely iodine-deficient areas in the world. As the amount of iodine depends on the soil that vegetation grows in, plants and vegetables in these regions have a low iodine concentration. Animals consuming food grown in these soils become iodine deficient too. As a result, the consumption of vegetables, plants and livestock from these regions cannot deliver daily iodine requirements.

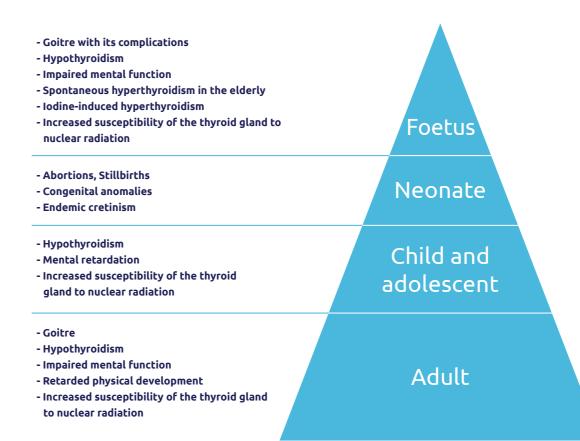
Symptoms of iodine deficiency

As a result if the recommended daily intake of iodine is not met, iodine deficiency may occur which can affect the production of thyroid hormones. If there are not enough thyroid hormones in the body it can lead to many adverse consequences relating to growth and development in humans. These effects are collectively termed as iodine deficiency disorders or IDDs. Common problems that can occur are endemic iodine-deficiency goitre or increased occurrence of an underactive thyroid gland (hypothyroidism) in

cases of moderate-to-severe iodine deficiency.

Typically symptoms of Hypothyroidism frequently include tiredness, problems with concentration, decrease in work productivity, apathy, reduced mental functions and lack of physical energy. A goitre is an enlargement of the thyroid gland beyond normal sizes. This enlargement is generally not cancerous but benign in nature.

Depending on the age, Iodine deficiency may lead to several disorders:



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Iodine status worldwide

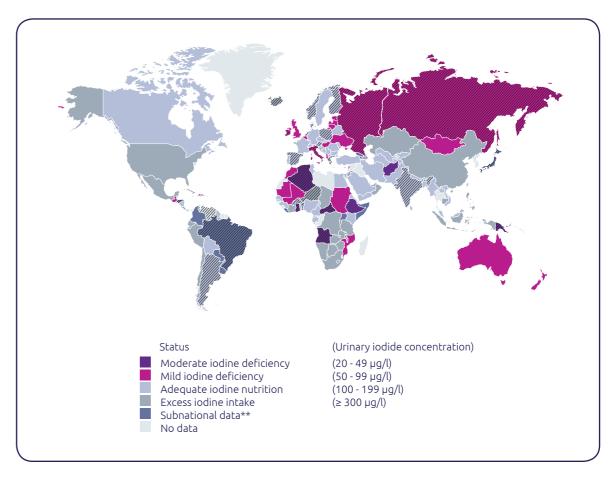
An estimated 1.6 billion people worldwide are at risk of iodine deficiency disorders. Data reports indicate that inhabitants in 21 countries suffer from mild iodine deficiency and nine of them are moderately iodine deficient. By comparison, more than 110 countries have adequate iodine intake. However in these countries some subgroups such as vegans, vegetarians, weaned infants or those who do not use iodised salt may still be deficient in iodine.

Europe has had the highest percentage of iodine-deficient children of school age compared with other WHO regions during the past deca-

de. This is surprising because of its wealth, its high standards of health care and also because of European calls to monitor and eliminate iodine deficiency. For example in 2015 only 66% of children of school age in the WHO-monitored European region had an adequate iodine intake. Similar results from another study of women has shown that iodine intake was adequate during pregnancy in only ten countries, whereas pregnant women in 21 countries get too little iodine. This means that in Europe twothirds of all women have an inadequate iodine intake during their pregnancy.



Global iodine status*



- * National iodide status based on median urinary iodide concentrations in children of school age
- ** Estimates based on subnational data. The national coverage relating to iodised salt in these countries is possibly incomplete and there may be large variations in iodine intake.

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Iodine during pregnancy

If you are pregnant your body undergoes various physical and physiological changes. The reason for these changes is not only to prepare the female body for the pregnancy, but also to assist the development of the unborn child. Some of the changes during pregnancy relate to the so called endocrine system which regulates a lot of functions in the body by producing certain hormones. For example, the production of thyroid hormones is higher in pregnant women which means that they also have an increased need for iodine during their pregnancy.

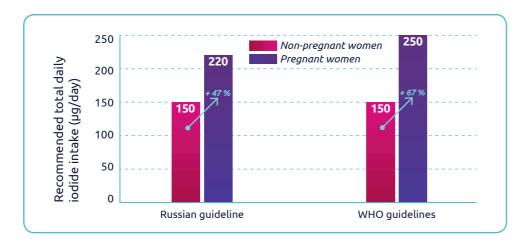
Furthermore thyroid hormones have distinct functions in the body during different growth phases of the foetus. In the course of pregnancy they regulate the growth and development of various organs, such

as the brain. Therefore they are very important for proper growth as well as physical and mental development in the foetus during pregnancy.

UNICEF, ICCIDD and WHO recommend a daily intake of 250 µg instead of 150 µg for non-pregnant women.*

As it could be hard to obtain these amounts of iodine through food, an iodine supplementation should be considered to achieve the higher requirement if you are pregnant.

According to the latest guideline of the American Thyroid Association in 2017, breastfeeding women should supplement their daily diet with 150 ug of iodine. This is optimally delivered in form of potassium iodide because kelp and other forms of seaweed do not provide a uniform quantity of daily iodine.



* Different agencies have recommended different intakes to meet iodine needs of pregnant women, ranging from 150 to 290 µg/day.



Iodine deficiency during pregnancy can lead to partially severe consequences for an unborn child including:

- Increased risk of stillbirths
- Impaired neurological development of the foetus
- Irreversible brain damage with mental retardation and neurological abnormalities

The most serious form of these irreversible derangements is so

called cretinism, which can lead to mental deficiency, deaf-mutism, spastic diplegia (a form of cerebral palsy), squinting and a short stature.

Not only can a severe deficiency have negative impacts on the foetus but even a mild to moderate iodine deficiency during pregnancy may affect the cognitive functions of a baby. This shows clearly how important it is to pay attention to your iodine intake during pregnancy.

According to the latest American Thyroid Association's guidelines from 2017, breastfeeding women should supplement their daily diet with 150 ug of iodine. This is optimally delivered in form of potassium iodide because kelp and other forms of seaweed do not provide a uniform quantity of daily iodine. 12

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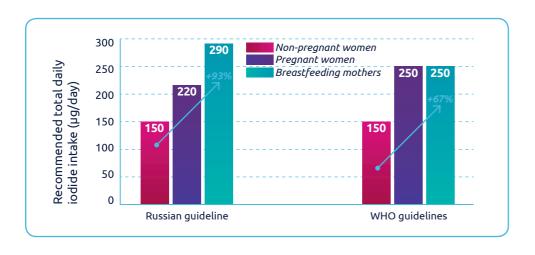
Iodine for breast-feeding women and newborns

Thyroid hormones have distinct functions in the body during different growth phases. In the early years of a new-born, they regulate the growth and development of various organs, such as the brain. Therefore these hormones are very important for proper growth as well as physical and mental development in children.

If you want to breast-feed your child after birth, your milk is the only major source of iodine for your infant in this important time, when iodine is needed for proper development of the brain and cognitive functions. So to assure that your child gets the best foundation for its later life, one step is to source enough iodine for yourself

and for your baby, which means your need for iodine intake also increases.

UNICEF, ICCIDD and WHO recommend a daily intake of 250 µg instead of 150 µg for adults in general. As it could be hard to obtain these amounts of iodine through food, an iodine supplementation should be considered to achieve the higher requirement if you are breast-feeding. And while continuing to breastfeed, babies aged 7 to 24 months should be given additional iodine via complementary foods fortified with iodine. If the child is not breast-fed, iodine supplementation should be considered from the beginning.





If you want to breast-feed your child, iodine is required for normal growth and development of breast tissue. One breast disease associated with iodine deficiency is fibrocystic breast disease or "diffuse cystic mastopathy".

This condition can lead to painful lumps in your breast, which can hurt during breast-feeding.

As your breast-feeding child gets all of its iodine via the breast milk, iodine deficiency in your body can lead to a reduced depot of neonatal thyroid hormone resulting in thyroid malfunctions. As the weeks after birth are an important period for brain development, iodine deficiency in this period can lead to impaired neurological development in the breast-fed child. Also mild to moderate iodine deficiency in early infancy can have adverse effects on the cognitive and motor performances of a baby. This means that the child may be prevented from attaining its full intellectual potential, iodine deficiency could also lead to thyroid function disorders.

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Iodine in children and teenagers

Thyroid hormones have distinctive functions in the body during different growth phases. In the early years of childhood, they regulate the growth and development of various organs, such as the brain or the central nervous system (CNS). Therefore they are very important for proper growth as well as physical and mental development in pre-school children. Likewise in adolescence, an adequate intake of iodine is recommended, as this a period of rapid growth when the body needs a lot of nutrients for a

proper development. The amount of iodine children on their age. The United Nations International Children's Fund for Control of Iodine Deficiency Disorders (ICCIDD) and the World Health Organization (WHO) for children up to age 59 months, 120 µg for children from 6 to 12 years and 150 µg for teenagers above 12 years.

and adolescents need daily depends (UNICEF), the International Council recommend a daily intake of 90 µg



Consequences of iodine deficiency for children and teenagers



Iodine deficiency in children leading to low thyroid hormones can be particularly serious: these hormones play a decisive role in the age-appropriate physical development and maturation processes. If children have a severe iodine deficiency it can lead to slower growth and disruption in the development of the brain and the CNS. This can lead to psychomotor defects such as the inability to stand and walk as well as o congenital malformations. The most serious form of these irreversible derangements is cretinism, which can lead to mental deficiency, deaf-mutism, spastic diplegia (a form of cerebral palsy with permanent movement disorder), squinting and short stature. A mild or moderate lack of iodine during the first years of a child can also affect a child's intellectual development.

Later during school years a lack of iodine can result in a significant loss of learning ability – up to 13.5 intelligence quotient points. Scientists also suspect an association between iodine deficiency and slower information processing, poor fine motor skills, and visual problems in school children. A severe iodine deficiency in adolescents can result in learning disability and a lower achievement. Other typical symptoms of iodine deficiency are, for example, tiredness, problems with concentration, apathy, reduced mental functioning and a lack of physical energy. All of these symptoms can have an negative impact on life quality of life and academic achievement.

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Prophylaxis of iodine deficiency

lodine deficiency disorders are widespread, but handling them once they become evident can cause uneasiness. Lack of iodine is not an acute disease but develops unnoticed over time.

So it can be sufficient to decide on preventive measures, especially in certain phases of life or when nutritional limitations exist.

Public health authorities give advice to counteract iodine deficiency, like consuming milk and dairy products dairy, eating saltwater fish at least once a week, using iodised salt and giving preference to foods including iodised salt.

But these recommendations are not as easy as they may sound for everybody – first you can never know how much iodine your meals contain exactly how much iodine your meals contain and therefore you cannot be sure if you get the right mount of daily iodine. And secondly specific groups of people need more daily iodine than others – like pregnant women. Then there are people with hypertension who often have to restrict their daily

salt intake. Those with specific food allergies such as cow's milk or fish may have problems sourcing recommended daily amounts of iodine because they have to avoid such foods. The same also applies to people who refrain from eating some or all animal foods like meat, fish, milk, and eggs. Vegetarians, vegans and people who have to keep to special diets have a greater iodine deficiency risk and need to be very careful to ensure that they get enough iodine. And the risk of developing iodine deficiency is very high for those living in parts of the world with a low iodine status where vegetables, plants and livestock only contain small amounts of iodine.





Oral supplementation with IODOMARIN®

Supplementation is an easy and effective method of acquiring an adequate amount of iodine and prevent iodine deficiency for all of these groups. If the WHO recommended intake is not fulfilled, a possibility is supplementation with Iodine tablet such as Iodomarin®.

Iodomarin® is a medicinal product and contains the active substance potassium iodide. It has two distinct therapeutic indication:

- Prophylaxis of iodine deficiency (e. g. prophylaxis of goitre in iodine deficiency areas and after removal of iodine deficiency goitre)
- Treatment of goitre in newborns, children, adolescents and young adults

In case the required amount of iodine in normal nutrition cannot be guaranteed, the iodine quantities set out below are to be administered additionally in order to prevent iodine deficiency.

Recommended Iodide intake according to the package leaflet of Iodomarin®.

- Infants and children: 50 to 100 µg Iodomarin® once daily
- Adolescents and adults: 100 to 200 µg Iodomarin® once daily
- Pregnant or breastfeeding women:
 200 µg Iodomarin® once daily

These doses may supplement the daily iodine requirement for you and serve as an easy and convenient way to prevent iodine deficiency and its consequences. Iodomarin® is available in two different dosages: Iodomarin® 100 with 131 µg potassium iodide (equivalent to 100 µg iodide) and Iodomarin® 200 with 262 µg potassium iodide (equivalent to 200 µg iodide). The two dosages of Iodomarin® offer you the right amount of iodine for your needs and help to restore the appropriate iodine level in your body. Thus Iodomarin® can prevent iodine deficiency and its consequences. In addition oral supplementation with tablets is one of the easiest ways to ensure getting the adequate quantity of iodine every day.

[country specific information]
Iodomarin® is a medication
that is trusted by both patients
and doctors. It has been on the
market for a long time and is
highly accepted as for iodine
supplementation.
[country specific information]

You will find more information about Iodomarin® 100 and 200 in the package leaflet and on our webpage www.iodomarin.[country code]

Library for further/ specified information

Iodine Dietary Supplement Fact Sheet for consumers from the NIH Office of Dietary Supplements, 2016.

Public Health Committee of the American Thyroid Association, Becker DV et al., Iodine supplementation for pregnancy and lactation – United States and Canada: recommendations of the American Thyroid Association. Thyroid. 2006;16:949-51.

Iodine related health claims. EFSA Journal 2009;7:1214.

Nussey S, Whitehead S. Endocrinology: An Integrated Approach. Oxford: BIOS Scientific Publishers; 2001. http://www.ncbi.nlm.nih.gov/books/ NB K28/#A280.

Andersson M et al. Iodine deficiency in Europe: a continuing public health problem. WHO Library Cataloguing-in Publication Data. 2007.

From the International Council for the Control of Iodine Deficiency Disorders (ICCIDD) Global Network website: http://www.iccidd.org/ p142000344.html.

Andersson M et al. (WHO Secretariat) Prevention and control of iodine deficiency in pregnant and lactating women and in children less than 2-years-old: conclusions and recommendations of the Technical Consultation. Public Health Nutr 2007;10:1606–1611.

Alexander EK et al. 2017 Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease During Pregnancy and the Postpartum. Thyroid. 2017; 27(3):315-389.

Zimmermann MB et al. Treatment of Iodine Deficiency in School-Age Children Increases Insulin-Like Growth Factor (IGF)-I and IGF Binding Protein-3 Concentrations and Improves Somatic Growth. The J of Clin Endocriniol and Metab, 92(2): 437-442.

Questions and answers on iodine intake and the prevention of iodine deficiency. Federal Institute für Risk Assessment, Berlin, Germany (http://www.bfr.bund. de/en/questions_and_answers_on_ iodine_intake_and_the_prevention_ of iodine deficiency-128779.html.

Iodomarin® 100 Package Leaflet (December 2012).

Iodomarin® 200 Package Leaflet

(December 2012).

correct mandatory text/legal disclaimer and minimum essential information about and minimum essentiar information abo the product according to the local law!



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