Fertilovit® FTHY Consumer Information

Food for special medical purposes for the dietary management of thyroid autoimmunity in women planning for pregnancy

lodine-free micronutrient combination with selenium, vitamin B12 and highly dosed folic acid. For coverage of the increased demand for B-vitamins, selenium and other vitamins and minerals.

When planning for pregnancy, every woman is recommended to be increasingly aware of a healthy lifestyle with a well-balanced and varied diet rich in minerals and vitamins. For optimal supply, supplementing important micronutrients can be a good option. Women with thyroid autoimmunity should be aware of their special requirements.

Fertilovit® FTHY is a food for special medical purposes tailored to meet the specific needs of women with thyroid autoimmunity planning for pregnancy. Thyroid autoimmunity results in chronic inflammation associated with elevated oxidative stress and hormonal dysbalances. As a consequence, women affected often suffer from disorders of oocyte maturation associated with irregular menstrual bleeding. The disorder leads to a specifically increased demand for for vitamins and minerals, whereas iodine has to be strictly avoided. Selenium in combination with vitamin B12, highly dosed folic acid and other nutrients cover this demand, thus supporting women with thyroid autoimmunity planning for pregnancy.

Thyroid autoimmunity and the desire for children

Chronic thyroid autoimmunity is an auto-immune disease of the thyroidea. It can occur in various forms. In Hashimoto's thyroiditis, the commonest form, the patient's body produces auto-antibodies directed against healthy thyroid cells, destroying them. As a consequence of this, thyroid hormone production decreases substantially (thyroid hypofunction or hypothyroidism). The rarer Graves' disease, on the other hand, is associated with the production of antibodies directed against a signaling molecule on the thyroid cells' surface. This causes the thyroid cell to produce an excessive amount of thyroid hormones (thyroid hyperfunction or hyperthyroidism). In the long run, however, many patients experience thyroid hypofunction as well.

It is estimated that one in six women have a predisposition for thyroid autoimmunity. However, it still is not clear which reasons and triggers are responsible for the onset of the disease. Scientific studies have found associations with a variety of factors, such as genetic factors, excess iodine exposure, changing levels of sexual hormones during pregnancy or menopause, smoking or radiation.

Symptoms are divers and vary individually

Thyroid hyperfunction is associated with symptoms such as sleeplessness, nervousness, hot flashes, rapid heartbeat and hair loss. Thyroid hypofunction on the other hand results in weight gain, fatigue and generally diminished performance, sensitivity to cold, diminished ability to concentrate and even depressive disorder.

Women who wish to conceive suffer particularly from diminished sexual desire, impaired menstrual cycles, decréased fertility and increased risk of miscarriage. In these cases fertility treatment with thyroid hormones can help to achieve healthy pregnancy. The patient herself can support therapy as well by taking into account her specific nutritional needs.

A diet low in iodine

According to scientific studies excessive iodine exposure worsens the progress of the disease. A diet low in iodine on the other hand has been reported to result in an improvement. Hence patients with autoimmune thyroiditis are recommended to abandon iodized table salt. Therefore, ${\bf Fertilovit}^{\otimes}$ ${\bf F}^{{\bf THY}}$ deliberately contains no indine

A diet low in gluten

Thyroid autoimmunity is often accompanied by coeliac disease. Even if coeliac disease can not be established, thyroid patients seem to benefit from a diet low in gluten. Consequently, Fertilovit® FTHY is gluten-free.

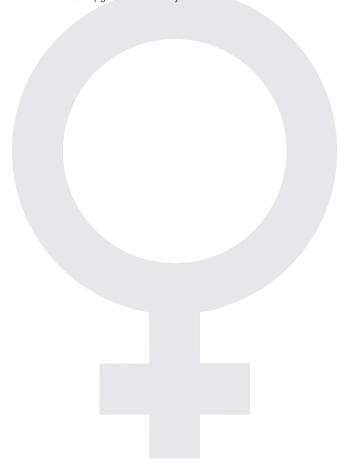
Specific nutrient deficiencies and oxidative stress

Even though the reasons for the onset of the disease are not quite understood, recent research has revealed oxidative stress to be an important contributing factor. The term oxidative stress refers to the impairment of body cells by reactive oxygen species (ROS). Oxidative stress increases the immunological turmoil which is associated with the inflammatory processes in the thyroid gland and many experts claim it to be responsible for a substantial part of the symptoms. Oocytes on the other hand are particularly susceptible to reactive oxygen species, too.

Thyroid autoimmunity is associated with an increased risk for deficiencies in selenium and zinc. Since these trace elements are components of antioxidant enzymes, the elimination of existing deficiencies is a central aspect of the dietary management of this disease. In addition, patients affected often also exhibit deficiencies in the B vitamins folic acid and vitamin B12. This has to be taken into account in the dietary management.

Folic acid

Like every woman planning for pregnancy, thyroid autoimmunity patients ought to make sure they get enough folate. This vitamin belongs to the B-group of vitamins. Even though it is abundant in green leafy vegetables, it is easily destroyed during storage and meal preparation due to its sensitivity to heat and light. Thus optimal supply is often difficult. In the case of healthy women planning for pregnancy usually an additional supply of 400 µg folic acid daily is recommended. Fertility patients often exhibit a genetic variant in the folate metabolism, which makes it necessary to administer 800 µg folic acid daily.



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Average nutritional values	Per 100 g	Per daily dose (1 capsule)
Energy	303 kJ (72 kcal)	2 kJ (0.4 kcal)
Fat of which saturates	O g O g	O g O g
Carbohydrate of which sugars	4.7 g O g	O g O g
Protein	О д	О д
Salt	0.04 g	Од
Vitamin D	2,703 μg	15 µg
Vitamin E	2,703 mg	15 mg
Vitamin C	18,018 mg	100 mg
Thiamin	721 mg	4.0 mg
Riboflavin	811 mg	4.5 mg
Niacin	3,063mg	17 mg
Vitamin B6	973 mg	5.4 mg
Folic acid	144,144 µg	800 µg
Vitamin B12	1,622 µg	9.0 µg
Biotin	27,027 μg	150 µg
Pantothenic acid	3,243 mg	18 mg
Magnesium	18,018 mg	100 mg
Iron	1,351 mg	7.5 mg
Zinc	414 mg	2.3 mg
Selenium	18,018 μg	100 µg
Sodium	14 mg	0.08 mg

Fertilovit® FTHY is free from artificial colours, suitable for vegans and gluten-free.

Administration form:

Capsules

Packaging sizes:

90 capsules, Three month pack 30 capsules, One month pack

Net quantities:

50 g

17 g

Ingredients

Magnesium oxide, L-ascorbic acid, hydroxypropyl methyl cellulose, citrate, calcium-D-pantothenate, coenzyme nicotinamide, D-alpha-tocopheryl acetate, pyridoxine hydrochloride, thiamine hydrochloride, riboflavin, zinc oxide, pteroylmonoglutamic acid, D-biotin, sodium selenite, cholecalciferol, carrot concentrate, cyanocobalamin, glazing agent ethyl cellulose.

Application:

For the dietary management of thyroid autoimmunity in women planning for pregnancy.

Please note:

Fertilovit® FTHY is a nutritionally incomplete food for special medical purposes. The product must be used under medical supervision. A varied and balanced diet as well as a healthy lifestyle are important. Please store out of reach of little children.

Signature:

Please take 1 capsule daily with plenty of water.

Warnings and precautions:

If you take thyroid hormones, do not take them at the same time as Fertilovit® FTHY. The iron in Fertilovit® FTHY may bind to the

hormones, making them ineffective.

Fertilovit® F^{THY} contains 150 µg biotin per capsule. If you are about to undergo laboratory testing, you must tell your doctor or the laboratory personnel that you are taking or have recently taken Fertilovit® F^{THY}, because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking **Fertilovit®** FTHY before performing laboratory tests.

Best before end:

The best before date is printed on the packaging.

Made in Germany

Sales and distribution:

Gonadosan Distribution GmbH Römerstrasse 2 6900 Bregenz Austria www.fertilovit.com

This product is protected by the European patent no. 2648807.

