

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### FAVISTAN

20 mg, tablets

### TIAMAZOL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

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#### What is in this leaflet?

1. What Favistan is and what it is used for
2. Before you take Favistan
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4. Possible side effects
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#### 1. WHAT FAVISTAN IS AND WHAT IT IS USED FOR

Favistan belongs to the group of medicines for the treatment of the thyroid gland. Tiamazol, the active ingredient of the medicine inhibits the excessive production of thyroid hormones and prevents increased activity of the thyroid gland.

#### **FAVISTAN 20 mg tablets are used for:**

- Treatment of increased activity of the thyroid gland, without the current enlargement or with a smaller enlargement of the thyroid gland;
- Preparation for the surgery of all forms of increased activity of the thyroid gland;
- Preparation for the treatment with radioactive iodine;
- Intermittent treatment after the treatment with radioactive iodine.

#### 2. BEFORE YOU TAKE FAVISTAN

Warn the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, you are hypersensitive to medicines or have had allergic reactions to some of them.

**Do not use Favistan:**

- If you are hypersensitive to thiamazole, carbimazole or any other substance of the medicinal product;
- If you have a disorder of the blood count (granulocytopenia);
- If after previous treatment with thiamazole or carbimazole you experienced damage to the bone marrow;
- If you have blocked bile flow (cholestasis).

Favistan in combination with thyroid hormones may not be used in pregnancy.

If you have any concerns, talk with your doctor or pharmacist before using this medicine.

**Take special care with Favistan**

Do not use Favistan if you have previously had allergic reaction to this medicine (for example, rashes, pruritus).

If you have an enlarged thyroid gland with a narrowing of the trachea, Favistan can be used only short term and under strict supervision of a doctor, due to the risk of the growth of the thyroid gland.

Before and during treatment with this medicine, it is necessary to regularly check blood count so that a doctor could observe any changes in a complete blood count (CBC).

**Special warning:**

In case of an elevated body temperature, pain in the throat, inflammation of the lining of the mouth, skin ulcers, immediately stop using Favistan and contact your doctor, because the specified symptoms may indicate a lack of white blood cell count (agranulocytosis).

**Using other medicines with Favistan**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Iodine deficiency increases and the excess of iodine reduce the response of the thyroid gland to thiamazole. Direct interactions with other medicines are not known. It is known that increased function of the thyroid gland may cause accelerated degradation and excretion of other medicines. But this process is normalized with the normalization of condition of the thyroid gland.

If any of the above applies to you or if you are not sure, consult your doctor before using this medicine.

**Taking Favistan with food and drinks**

There are no special warnings.

**Pregnancy and breastfeeding**

Before you start taking any medicine, consult with your doctor or pharmacist.

**Pregnancy**

Because of the potential harm to the unborn child, FAVISTAN 20 mg tablets can be used only with doctor's explicit recommendation, and only after the doctor has carefully assessed that the potential benefit for the mother exceeds the possible risk for the fetus. If the therapy with thiamazole is still necessary during pregnancy, the lowest possible effective dose should be used. Additional therapy with thyroid hormones should not be used.

**Breast feeding**

Thiamazole is excreted into breast milk, and there is a risk of decreased activity of the thyroid gland in infant. Thiamazole can be used during breastfeeding, but in smaller doses (up to 10 mg per day) without the use of

additional hormones of the thyroid gland. In this case, the function of the thyroid gland in infant needs to be regularly checked.

### ***Driving and using machines***

Favistan has no impact on your ability to drive and use machines.

### ***Other warnings***

Favistan contains lactose and sucrose. If your doctor told you that you have intolerance to some sugars, consult your doctor before using this medicine.

## ***3. HOW TO TAKE FAVISTAN***

Take the medicine according to the instructions.

If you think that the effect of the medicine is too strong or too weak, you should consult with a doctor or pharmacist.

If you are not sure and if you have concerns related to the use of the medicinal product, consult with your doctor or pharmacist.

### ***Method of administration***

Swallow the tablet without chewing with a sufficient amount of fluids (preferably water).

### ***Dosage and duration of the treatment***

The treatment of the increased activity of the thyroid gland

Depending on the severity of illness, the recommended starting dose of thiamazole is 1 to 2 tablets (equivalent to 20 to 40 mg of thiamazole) a day, divided into several individual doses.

With the improvement of the condition, after a period of 3 to 8 weeks, your doctor will adequately reduce the dose. Maintenance dose, which according to the recommendation of the doctor should be taken for one to two years, is from 2.5 to 10 mg of thiamazole a day. In some cases maintenance dose may be higher.

This dose may be administered at once, preferably in the morning, possibly together with thyroid hormone, which is decided by your doctor. Higher doses are necessary in the case of particularly serious illness, especially in increased function of the thyroid gland caused by iodine application.

After achieving normal thyroid function (euthyroid state) your doctor may include additional treatment with thyroid hormones. A dose of 50 to 100 micrograms of levothyroxine sodium per day.

Preparation for surgery for all forms of increased function of the thyroid gland

In preparation for the surgical treatment of increased function of the thyroid gland, FAVISTAN 20 mg tablets are applied until the surgery (a mixture of iodine can be added 10 days before the operation, and in case that there is more time before the operation, thyroid hormones can be added too).

Application before the treatment with radioactive iodine

The dosage and duration of treatment will be determined by the doctor who is responsible for the treatment with radioactive iodine.

### ***Intermittent treatment after treatment with radioactive iodine***

The dosage and duration of treatment will be determined by your doctor.

### ***Dosage during pregnancy and during lactation***

The minimum dose should be used in pregnant women (2.5-10 mg thiamazole). Treatment should be carried out without the addition of thyroid hormones.

The maximum dose during breastfeeding is 10 mg.

### ***Dosage in patients with impaired liver function***

It is necessary to reduce the dose.

### ***If you use more Favistan than you should***

If you take more than the prescribed dose of the medicine, immediately contact your doctor or pharmacist!

High doses of the medicine may reduce the function of the thyroid gland and diffuse the growth of the thyroid gland. Therefore, once you establish normal function of the thyroid gland, the dose should be reduced and / or additional therapy with thyroid hormones should be applied. It is not advisable to stop the treatment and resume taking only with thyroid hormones.

### ***If you forget to use Favistan***

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

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

### ***If you stop using Favistan***

Use this medicine for as long as your doctor has prescribed.

Do not change the method of administration and do not stop using the medicine before you inform the doctor.

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

## ***4. POSSIBLE SIDE EFFECTS***

Like all medicines and Favistan may cause side effects.

Side effects are classified according to the frequency of occurrence in the following way:

**Very common:** occurs in more than 1 in 10 patients

**Common:** occurs in 1 to 10 in 100 patients

**Uncommon:** occurs in 1 to 10 in 1000 patients

**Rare:** occurs in 1 to 10 to 10000 patients

**Very rare:** occurs in less than 1 in 10000 patients

**Unknown frequency:** cannot be estimated on the basis of the available data.

### ***Blood and lymphatic system***

**Uncommon:** lack of white blood cells (agranulocytosis).

Agranulocytosis is manifested in the form of inflammation of the lining of the mouth, inflammation of the throat, elevated body temperature, or the advent of purulent ulcers on the skin. If you spot any of these occurrences with the use of the medicine you should discontinue the treatment immediately, especially during the first week of administration. Talk to your doctor to control blood count. Agranulocytosis symptoms may occur weeks or months after administration of the medicine.

**Very rare:** a reduction in the number of platelets and other blood elements, enlarged lymph glands (generalized Lymphadenopathy).

### ***Disorders of the immune system***

**Very rare:** disorders of a hormone that regulates the level of sugar in the blood with a reduction of the sugar levels (insulin autoimmune syndrome).

### ***Disorders of the endocrine system***

Excessive dosage of the medicine may lead to reduction in the function of the thyroid gland and the occurrence of goiter due to the growth of levels of the thyreostimulating hormone (TSH). Because of this, as soon as you establish the normal function of the thyroid gland, dose should be reduced, and if necessary, additional hormones of the thyroid gland should be applied. It is not recommended to interrupt therapy with tiamazol and continue only with the application of hormones of the thyroid gland.

Further growth of already enlarged thyroid gland with reduced levels of the hormone that stimulate the work of thyroid gland (thyroid stimulating hormone-TSH) is probably a consequence of the disease and cannot be prevented by additional treatment with thyroid hormones.

It is unlikely that during treatment only with thiamazole later disorders of thyroid function occur; in this case it is not about the possible side effects of the medicine but the inflammatory processes in the tissues of the thyroid gland caused by the underlying disease.

### ***Disorders of the nervous system***

**Uncommon:** taste disturbance, i.e. a disorder of smell, which is normalized after the end of treatment.

**Very rare:** inflammation of the nerves (neuritis) and polyneuropathy (global disorder of sensation of the skin, abnormal sensibility, inflammatory and degenerative diseases of the peripheral nerves).

### ***Eye disorders***

Phenomena of deterioration of eye diseases typical for patients with increased function of the thyroid gland (endocrine ophthalmopathy), is mostly independent from the flow of the diseases of the thyroid gland. Such complications by itself are not a reason to change the regime of treatment and should not be considered as side effects if treatment is carried out properly.

### ***The blood-vascular disorders***

**Very rare:** an inflammation of the blood vessels.

### ***Disorders of the digestive system***

**Very rare:** acute swelling of the salivary glands.

### ***Hepatobiliary disorders***

**Very rare:** jaundice due to disorders of the bile flow or toxic inflammation of the liver. Symptoms are, for the most part, retreating after the termination of the use of the medicine.

### ***Disorders of skin and subcutaneous tissue***

**Very common:** the emergence of allergies (itching, rash, redness, swelling) of different degrees, usually in mild form, and the symptoms often retreat during treatment.

**Very rare:** severe forms of skin allergic reactions including inflammation that overtakes the entire skin surface (generalized dermatitis), hair loss (alopecia), inflammation and damage to connective tissue disorders (lupus erythematosus) caused by tiamazol .

### ***Disorders of the musculoskeletal system and connective tissue***

**Very rare:** inflammation of the joints (arthritis), joint pain and muscle pain (arthralgia and myalgia) can arise gradually and appear even after a few months of therapy. Clinical signs of arthritis are not expressed.

### ***Disorders of the kidneys and urinary tract***

**Very rare:** inflammation of the kidneys.

### ***General disorders and reactions at the administration site***

**Uncommon:** high temperature caused by the medicine, swelling.

It is possible to gain weight during treatment with FAVISTAN 20 mg tablets. This is a normal reaction of your body, because the medicine FAVISTAN 20 mg affects the thyroid hormones that control energy consumption in your body.

It is believed that all the above mentioned side effects depend on the dosage, but occur mainly during the first weeks of therapy.

If you notice any side effect, talk to your doctor or pharmacist.

## ***5. HOW TO STORE FAVISTAN***

Keep out of reach and sight of children.

Keep at temperature below 25 ° c.

Favistan should not be used after the expiry date stated on the carton.

The shelf life of the medicinal product is 5 years from the date of manufacture, which is indicated on the package.

## ***6. FURTHER INFORMATION***

### ***What Favistan contain***

One FAVISTAN Tablet contains: tiamazol 20.00 mg.

The other ingredients are: lactose, calcium phosphate dibasic dihydrate, corn starch, sucrose, sugar, talc and iron oxide yellow (E172).

### ***How Favistan looks like and contents of the pack***

Favistan tablets are beige, round in shape with imprinted divisional cross on one side.

Favistan tablets are packed in the box with 20 tablets.

### ***Regime of dispensing***

The medicine is issued to the doctor's prescription

### ***Manufacturer***

Bosnalijek d.d., Sarajevo, Jukićeva 53, Bosnia and Herzegovina

### ***Manufacturer of the medicinal product***

Bosnalijek d.d., Sarajevo, Jukićeva 53, Bosnia and Herzegovina