PACKAGE LEAFLET: Information for the patient

STOMAKURAN

Suspension – 40%

(Sulfanilamide)

Read all of this leaflet carefully before you start using this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT STOMAKURAN IS AND WHAT IT IS USED FOR

Stomakuran contains sulfanilamide as active substance, which is an antibacterial often used against gram-negative organisms. Sulfanilamide destroys or stops the replication of bacteria by blocking para-aminobenzoic acid at bacteria, which is necessary for the synthesis of folic acid.

Stomakuran is used for the treatment of lesions of the oral cavity, especially in cases of acute follicular tonsillitis and *Str. haemolyticus*.

2. BEFORE YOU USE STOMAKURAN

Do not use Stomakuran:

- if you are hypersensitive (allergic) to sulfanilamide or to any of the other ingredients of Stomakuran;
- if you have well vascularized oral mucosa, particularly when you have temperature or after taking sublingual nitroglycerin when you suffer from angina pectoris.

It is not recommended to use Stomakuran during pregnancy and breast-feeding.

Take special care with Stomakuran

Ask your doctor before using Stomakuran.

The active substance of Stomakuran, sulfanilamide, is a short-acting sulfonamide.

- Treatment with sulfonamides should be stopped immediately if rash appears due to the risk of development of severe allergic reactions such as Stevens-Johnson syndrome.
- Sulfonamides are not usually given to infants within to 2 months of birth because of the possibility of producing kernicterus; for the same reason, they are generally contraindicated in women prior to delivery.

Taking other medicines

Tell your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Stomakuran if you are given another drug during treatment.

Stomakuran contains sulfanilamide as active substance which is a sulfonamide.

- Sulfanilamide should not be taken at the same time with sublingual nitroglycerin, since during angina pectoris oral mucosa is well vascularized.
- The action of sulfonamides may be antagonised by para-aminobenzoic acid and its derivatives, particularly potassium aminobenzoate and the procaine group of local anaesthetics.
- Sulfonamides may potentiate the effects of some drugs, such as oral anticoagulants, methotrexate, and phenytoin.
- The possibility of interactions with other highly protein-bound drugs, such as NSAIDs, should be considered.

- Sulfonamides have been reported to interfere with some diagnostic tests, including those for urea, creatinine, and urinary glucose and urobilinogen.

Using Stomakuran with food and drinks

It is not recommended to take food and drinks while applying Stomakuran to oral mucosa because in this way sulfanilamide is removed by the sputum from oral cavity mucosa.

Pregnancy

There is a risk of fetal damage from sulfanilamide.

It is not recommended to use Stomakuran during pregnancy. Sulfonamides, the group where it belongs, may displace serum-bound bilirubin. For this reason they should be avoided during pregnancy, particularly close to delivery because of the risk of kernicterus in the neonate. Sulfonamides should be used during pregnancy only in the absence of an alternative drug. Therefore, always consult with your doctor before using Stomakuran during pregnancy.

Breast-feeding

Sulfanilamide, even though may be minimally absorbed, it passes into breast milk and for this reason should not be used during breast-feeding.

Driving and using machines

There are no data available showing that this medicine may influence the ability to drive or use machines.

3. HOW TO USE STOMAKURAN

Always use Stomakuran as prescribed by your doctor. If you are not sure, contact with your doctor or pharmacist. If you feel that the effects of Stomakuran are too weak or too strong, talk to your doctor or pharmacist.

Stomakuran is a suspension which should be well-shaken before use until it is completely homogenized. Then, it can be applied with a cotton pad to the oral mucosa and gingiva.

If you use more Stomakuran

If you use more Stomakuran than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

The data about overdosage with sulfanilamide are limited. Overdosage may be associated with an extension of adverse events reported with sulfonamides. Methemoglobinemia has been reported after overdose.

If you forget to use Stomakuran

If you forget to use one dose, use the next dose at its usual time. Do not use a double dose to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

Most of the side effects are dose related and disappear when the dose is reduced or the the treatment is stopped. Some side effects may appear in the beginning of the treatment and disappear spontaneously during treatment.

The most usual reactions are the allergic reactions such as: acne, urticaria, swelling of the mouth, face, lips and tongue.

Sometimes unusual itching, temperature and burns may appear.

Sulfonamides may displace serum-bound bilirubin, resulting in kernicterus in neonates.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE STOMAKURAN

Keep this medicine out of the reach and sight of children!

Do not use Stomakuran after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light.

Close well the bottle after using it.

6. FURTHER INFORMATION

What Stomakuran contains

The **active substance** is sulfanilamide.

Each bottle contains 40 % sulfanilamide (6 g / 15 g suspension).

The **other ingredients** are: ethacridine lactate, methylene blue, 8-hydroxyquinoline sulphate, salvia officinalis extract, chamomillae extract, nitrofurazone, polysorbate 80, glycerin, purified water, ethanol.

Contents of the pack

Carton box with one bottle with a content of 15 g.

Marketing Authorisation Holder (MAH) and Manufacturer

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Tirana, Albania.
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