Package leaflet: Information for the patient

Sodium Perchlorate Dyckerhoff 300 mg/ml oral drops

For use in children and adults

Active substance: Sodium perchlorate

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. See section 4.

What is in this leaflet

1. WHAT SODIUM PERCHLORATE DYCKERHOFF IS AND WHAT IT IS USED FOR

Sodium Perchlorate Dyckerhoff is a medicine that inhibits the formation of thyroid hormones. In case of an overactive thyroid, increased amounts of thyroid hormones are produced and released. The initial symptoms include watery eyes, increased pulse rate, restlessness, trembling of the fingers and sweating attacks. An overactive thyroid can lead to goitre.

Sodium perchlorate blocks the iodine uptake into the thyroid by competing with iodine for transport into the thyroid (competitive inhibition).

Blocking the thyroid is also necessary when radioactive iodine is used for an examination or for the treatment of other organs. This prevents the radioactive iodine from accumulating primarily in the thyroid.

Sodium Perchlorate Dyckerhoff is used
- For the treatment of an overactive thyroid.
- To block the thyroid in case of an examination or treatment of other organs with a medicine that contains radioactive iodine (e.g. scintigraphic examination or radionuclide therapy).
- To block the thyroid when administering X-ray contrast media that contain iodine.
- For a perchlorate discharge test (examination to detect a congenital defect in the incorporation of iodine into the thyroid; defective iodine metabolisation).
- For blocking the thyroid upon advice by the competent authorities during an emergency involving the release of radioactive iodine, in patients not allowed to take potassium iodide.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SODIUM PERCHLORATE DYCKERHOFF

Sodium Perchlorate Dyckerhoff must not be taken,

- if you are allergic to perchlorate or any of the other ingredients of this medicine listed in section 6.
- if you have previously experienced a change in your blood count while taking perchlorate, particularly agranulocytosis (severe reduction in certain blood cells)
- if you have been administered iodine in preparation of surgery (Plummer's treatment)
- if you have a goitre behind the sternum or clavicles (retrosternal goitre)

Warnings and precautions

Talk to your doctor or pharmacist before taking Sodium Perchlorate Dyckerhoff.

When treating an overactive thyroid with Sodium Perchlorate Dyckerhoff, the thyroid function should be checked regularly and the dose of Sodium Perchlorate Dyckerhoff should be adjusted accordingly to prevent an enlargement of the thyroid or signs of an underactive thyroid.

Your doctor will perform regular blood counts to assess potential blood count changes. If you experience fever, sore throat or inflammation of the mucous membranes of the mouth during treatment with Sodium Perchlorate Dyckerhoff, this might be a first sign of a blood count change. In such cases, please contact your doctor immediately!

Serious, sometimes life-threatening skin reactions (Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) with a skin rash that can lead to a widespread blistering or peeling of the skin have been reported in association with Sodium Perchlorate Dyckerhoff (see section 4). If you develop a skin rash or other skin reactions mentioned in section 4 stop taking this medicine and contact your doctor immediately. If you have experienced a severe skin reaction associated with the use of sodium perchlorate, you should never be treated with sodium perchlorate again.

Other medicines and Sodium Perchlorate Dyckerhoff

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

Sodium Perchlorate Dyckerhoff should be discontinued at least three days prior to conducting a thyroid scintigraphy or radionuclide measurement (examination with a radioactively labelled substance).

Sodium Perchlorate Dyckerhoff does not affect the TSH modulated radioiodine absorption into the thyroid.

The following medicines might influence the effect of Sodium Perchlorate Dyckerhoff or might themselves be influenced by Sodium Perchlorate Dyckerhoff.

- Uptake of radioiodine or ^{99m}Tc-pertechnetate (radioactively labelled substances) is dose-dependently inhibited.
- Co-administration of iodine-containing medicines or contrast media reduces the effect of Sodium Perchlorate Dyckerhoff.
- Simultaneous use of other medicines for the treatment of an overactive thyroid (antithyroid drugs, propylthiouracil, thiamazole, carbimazole) amplifies the effect of Sodium Perchlorate Dyckerhoff.

- Simultaneous use of thiamazole (antithyroid drug) causes a positive perchlorate discharge test, even in healthy subjects and in patients with an overactive thyroid, since iodine absorption is inhibited by thiamazole.

Please note that this information might also apply to recently administered medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
You should not take Sodium Perchlorate Dyckerhoff during pregnancy as there is insufficient experience concerning the possible risk to the unborn child.
Breast-feeding should be discontinued, if a treatment with Sodium Perchlorate Dyckerhoff is required during breast-feeding.

Driving and using machines
Sodium Perchlorate Dyckerhoff has no influence on the ability to drive or use machines.

3. HOW TO TAKE SODIUM PERCHLORATE DYCKERHOFF

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The following information applies, unless your doctor has prescribed otherwise. Please follow the dosing instructions from your doctor, otherwise Sodium Perchlorate Dyckerhoff cannot act properly!

Your doctor will decide how long you should use Sodium Perchlorate Dyckerhoff. Please talk to your doctor or pharmacist if you have the impression that the effect of Sodium Perchlorate Dyckerhoff is too strong or too weak.

How often and how much Sodium Perchlorate Dyckerhoff you should take

Treatment of an overactive thyroid
Adults receive 10 drops 4 to 5 times a day (equivalent to 800 to 1000 mg sodium perchlorate per day) as an initial dose for the first 1 to 2 weeks, and in exceptional cases 15 drops 5 times a day (equivalent to 1500 mg sodium perchlorate per day). Generally, the maintenance dose is 5 drops 4 times a day (equivalent to 400 mg sodium perchlorate per day).
Children aged 6 to 14 years receive 1 to 2 drops 3 to 6 times daily (equivalent to 60 to 240 mg sodium perchlorate per day, maintenance dose).

In case of an examination or treatment with a medicine that contains radioactive iodine (e.g. scintigraphic examination or radionuclide therapy)
In adults, the recommended dose is 10 to 30 drops daily (equivalent to 200 to 600 mg sodium perchlorate), in individual cases up to 50 drops (equivalent to 1000 mg sodium perchlorate).
Children under 2 years: 5 drops (equivalent to 100 mg sodium perchlorate).
Children aged 2 to 12 years: 10 drops (equivalent to 200 mg sodium perchlorate).
Alternatively in children, approx. 1 drop per 3 kg body weight (usually at least 10 drops, not more than 20 drops) divided into 4 to 6 individual doses per day, starting at least 60 minutes before ^{123}I-mIBG administration (according to the guideline "Performing and interpreting ^{123}I-mIBG scintigraphy in children and adolescents" by the German Society for Nuclear Medicine).
Your doctor will decide how long you should use Sodium Perchlorate Dyckerhoff taking into account the product information for the radioactive medicine that was used for the examination or the relevant clinical guidelines. In general, to reduce radiation exposure to the thyroid, it is recommended to take Sodium Perchlorate Dyckerhoff daily

- at least 60 minutes before administering the radioactive medicine
- and for up to 5 days following an examination involving a radioactive medicine
- or for 2 to 3 weeks following radionuclide therapy.

When administering X-ray contrast media that contain iodine
Adults: 30 drops (equivalent to 600 mg sodium perchlorate) 2 to 4 hours before contrast media administration and again after contrast media administration; afterwards 15 to 20 drops 3 times a day (equivalent to 900 mg to 1200 mg sodium perchlorate per day) for 7 to 14 days. The thyroid function should be checked after 4 weeks.

For a perchlorate discharge test
Sodium Perchlorate Dyckerhoff is taken once after administration of the radioiodine.
For adults: single dose of 30 to 50 drops (equivalent to 600 to 1000 mg sodium perchlorate).
Children receive a single dose of 15 to 30 drops (equivalent to 300 to 600 mg sodium perchlorate) per m^2 body surface area.

For blocking the thyroid during an emergency involving the release of radioactive iodine
For blocking the thyroid upon advice by the competent authorities during an emergency involving the release of radioactive iodine, in patients not allowed to take potassium iodide, the German Radiation Protection Commission recommends the following doses of sodium perchlorate, which should ideally be taken only a few hours before exposure to radioactive iodine:
Adults: single dose of 30 to 50 drops (equivalent to 600 mg to 1000 mg sodium perchlorate)
Children: single dose of 15 to 30 drops (equivalent to 300 mg to 600 mg sodium perchlorate) per m^2 body surface area.
In case of a repeated or long-lasting release of radioactive iodine or if the release occurs more than a few hours after taking sodium perchlorate, it may be necessary to take sodium perchlorate again after 24 hours in analogy to iodine thyroid blocking.

Method and route of administration
Sodium Perchlorate Dyckerhoff should be taken with plenty of water, preferably after a meal, to prevent gastrointestinal side effects.
Please adhere to the dosing frequency recommended by your doctor, e.g. multiple doses spread over the day.

Turn the bottle completely upside down.
If no drops come out, tap the bottle lightly to start the flow.

If you take more Sodium Perchlorate Dyckerhoff than you should
There are no negative effects known following an accidental intake of high doses of Sodium Perchlorate Dyckerhoff. Overdose of Sodium Perchlorate Dyckerhoff over a long period of time leads to hypothyroidism and subsequent goitre. Therefore, the dose must be reviewed regularly.

If you forget to take Sodium Perchlorate Dyckerhoff
Please follow your doctor's instructions so that the medicine can act properly. If you miss a dose, do not subsequently take a higher dose, continue with the next dose as intended.

If you stop taking Sodium Perchlorate Dyckerhoff
Please do not pause or discontinue your treatment with Sodium Perchlorate Dyckerhoff without talking to your doctor.

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

4. POSSIBLE SIDE EFFECTS

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

The following frequencies are defined for the classification of side effects:

Common:	less than 1 in 10 but more than 1 in 100 patients
Uncommon:	less than 1 in 100 but more than 1 in 1,000 patients
Rare:	less than 1 in 1,000 but more than 1 in 10,000 patients
Very rare:	less than 1 in 10,000 patients, or unknown

Possible side effects

The occurrence of side effects is dose-dependent.

Common
Fleeting skin rash, nausea or vomiting, dry mouth, irritation of the throat mucosa, lymph node swelling, low white blood cell count (leukopenia), skin and mucous membrane bleeding (purpura), febrile joint pain, drug fever.

Uncommon
Diarrhoea at the beginning of treatment, slight muscle cramps, burning feet, heaviness in the head, itching, jaundice (icterus), proliferation of certain white blood cells (eosinophilia), bone marrow damage with a much lower white blood cell count (agranulocytosis), which usually resolves rapidly and without consequences after discontinuing Sodium Perchlorate Dyckerhoff.

Very rare
Bone marrow damage with fatal outcome, low blood platelet count (thrombocytopenia) or low red blood cell count (aplastic anaemia) with fatal outcome, protein in the urine (albuminuria), kidney disease with complete or partial recovery (nephrotic syndrome), hair loss, acne and other types of skin inflammation, hives, liver damage with acute liver failure, perforation of a duodenal ulcer, inflammatory nodules under the skin (erythema nodosum) with fever attacks and antibodies in the blood directed against cell nuclei and red blood cells as well as eosinophilia.

For most of these extremely rare events observed during perchlorate treatment, a causal relationship to perchlorate was not established.

Not known (frequency cannot be estimated from the available data):
Severe skin reactions including skin rashes or redness, conjunctivitis (red and swollen eyes), widespread blisters or peeling skin, as well as ulcers of the mouth, throat, nose and genitals (Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) with life-threatening progression in individual cases (see section 2).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the
German Federal Institute for Drugs and Medical Devices (BfArM), Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany. Website: www.bfarm.de

By reporting side effects you can help provide more information on the safety of this medicine.

What actions should be taken in case of side effects?
Please inform your doctor if you get any side effects, so that your doctor can decide on any necessary actions.

If you experience any fever, sore throat or oral mucous membrane inflammation during treatment with Sodium Perchlorate Dyckerhoff, this might be a first sign of a change in blood count. In this case, please contact your doctor immediately!

5. HOW TO STORE SODIUM PERCHLORATE DYCKERHOFF

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 carton and the label.
The expiry date refers to the last day of the month.

Storage conditions
This medicinal product does not require any special storage conditions.

Shelf-life after first opening
After first opening the bottle, do not use for longer than 26 weeks when stored at room temperature.

Disposal
Do not throw away any medicines via wastewater. 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 Sodium Perchlorate Dyckerhoff contains
The active substance is sodium perchlorate.

1 ml of solution (about 15 drops) contains 300 mg sodium perchlorate (as sodium perchlorate 1 H_2O)

The other ingredients are:
Ammonium chloride, magnesium chloride, calcium chloride, purified water.

What Sodium Perchlorate Dyckerhoff looks like and contents of the pack
Sodium Perchlorate Dyckerhoff is a clear, colourless solution.
Sodium Perchlorate Dyckerhoff is available in a bottle containing 20 ml of solution.

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