

REXE-DINE

For the use of registered Medical Practitioner or Hospital or a Laboratory only.

REXE-DINE Mouth wash/ Gargle Solution

Composition:

Active substance: Povidone Iodine B.P 1% w/v

Broad-spectrum microbicide.

For use on the mucous membranes of the mouth and throat.

Indications:

For the treatment of infected, inflammatory conditions of the mouth and pharynx including stomatitis, gingivitis, aphthous ulcers, pharyngitis, tonsillitis, monilial infections, common colds and influenza.

As a prophylactic during and after surgery e.g. After tonsillectomy and dental procedures.

Routine use to promote oral hygiene.

Contraindications

Not to be used in the hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid diseases, the very rare chronic skin inflammation dermatitis herpetiformis Duhring, in known hypersensitivity to iodine as well as before and after radiotherapy of the thyroid gland with iodine (radioiodine therapy), until a lasting cure has been obtained.

Patients with goitre or following thyroid disease and also patients with a particular predisposition for disturbances of the thyroid function (especially elderly patients) are at risk of developing thyroid hyperfunction (hyperthyroidism). **Rexe-Dine Mouthwash/ gargle** should therefore not be used over a long period (not longer than 14 days) unless strictly instructed.

In patients undergoing concomitant lithium therapy, regular use of **Rexe-Dine Mouthwash/ gargle** should be avoided.

During pregnancy and lactation, **Rexe-Dine Mouthwash/ gargle** should only be used if strictly prescribed by the doctor and its use should be kept to absolute minimum. This also applies to the newborns and infants up to the age of 6 months. In these cases a check of the child's thyroid function is necessary. Also, any possible ingestion of the solution by the infant must be absolutely avoided.

Side effects:

Very rarely, hypersensitive skin reactions may occur (e.g. Delayed contact allergic reactions. Which can appear in the form of itching, redness, small blisters or similar manifestations).

The long term use of **Rexe-Dine Mouthwash/ gargle** can lead to notable uptake of iodine. Excessive absorption of iodine may produce systemic adverse effects such as metabolic acidosis, hypermatraemia and impairment of renal function. In isolated cases, patients with a history of thyroid disease can develop hyper function of the thyroid (iodine - induced hyperthyroidism), sometimes with symptoms such as racing pulse or a feeling of unrest (see under contraindications). If you experience any of these symptoms, you should immediately consult your doctor.

Interaction with other drugs:

The concomitant use of wound-treatment preparations containing a so-called enzymatic component leads to a weakening of the effects of both substances. The same thing can happen if you use hydrogen peroxide or taurolidine concomitantly with **Rexe-Dine Mouthwash/ gargle**.

Note: Due to the oxidative effect of **Rexe-Dine Mouthwash/ gargle** various diagnostic agents can show false-positive results (e.g. Test with toluidine or gum guaic for the determination of haemoglobin or glucose in the stool or the urine).

During the use of **Rexe-Dine Mouthwash/ gargle** the iodine uptake of the thyroid can be lowered; this can lead to interference with various investigations (thyroid scintigraphy, determination of PBI (protein bound iodine), radioiodine diagnostics) and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible. After the end of the treatment, an interval of at least 1-2 weeks should be allowed before new scintigram is carried out.

Dosage instructions and mode of application:

Precautions:

With false teeth, braces etc, the material from which they are made can sometimes become discoloured. It is therefore recommended to remove false teeth, braces etc. from the mouth before using **Rexe-Dine Mouthwash/ gargle**.

Use undiluted or diluted with an equal volume of warm water.

For prophylactic use, the solution should be allowed to act in the mouth for a minimum of 30 seconds.

With existing lesions the mouth should be rinsed with the solution for 2 minutes, several times a day (especially after meals).

When using **Rexe-Dine Mouthwash/ gargle** in small children, care should be taken to ensure that it is used strictly in accordance with the instructions (the solution must not be swallowed).

If there is no improvement of the symptoms after several days (2-5 days) regular use of the product, consult a doctor.

Presentation:

100 ml in amber colored Pet bottles and 250 ml in black plastic bottles.

Storage:

Do not store above 30° C. Store in a dry place. Protect from direct sunlight. Do not use after the expiry date

Keep all medicines out of reach of children.

Manufactured by:

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