

# Perchloracap<sup>®</sup>

Package inserts are current as of January, 1997. Contact Professional Services,  
1-888-744-1414, regarding possible revisions

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#### DESCRIPTION

Perchloracap is supplied for use during diagnostic studies as an opaque gray gelatin capsule for oral administration. Each capsule contains 200 milligrams of potassium perchlorate ( $\text{KClO}_4$ ) mixed with an inert filler.

#### CLINICAL PHARMACOLOGY

Orally administered potassium perchlorate is absorbed through the gastrointestinal tract. Having thus been introduced to vascular circulation, the perchlorate ( $\text{ClO}_4^-$ ) ion effects a suppression of the accumulation of the pertechnetate ( $\text{TcO}_4^-$ ) ion in the choroid plexus and the salivary and thyroid glands.

It is believed that the mechanism for this blocking effect is the release of  $\text{TcO}_4^-$  from the plasma binding sites through the competitive displacement by the perchlorate ( $\text{ClO}_4^-$ ) ion, with a resulting redistribution to tissue extracellular spaces and a shift of a portion of the  $\text{TcO}_4^-$  intracellularly, that is, from plasma to the red cell.

Following oral ingestion, maximum blood concentration of potassium perchlorate occurs at three hours. Perchlorate is excreted in the urine unchanged with 30 percent recovered in three hours, 50 percent in five hours, 85 percent in 24 hours and 95 percent in 48 hours. Potassium perchlorate is taken up by the choroid plexus 30 to 60 minutes after oral administration and blockage has been reported for six hours.

#### INDICATIONS AND USAGE

Potassium perchlorate should be administered to minimize the accumulation of pertechnetate Tc 99m in the choroid plexus and in the salivary and thyroid glands in those patients receiving Sodium Pertechnetate Tc 99m injection for brain and blood pool imaging and placenta localization.

#### CONTRAINDICATIONS

None.

#### WARNINGS

Potassium perchlorate has been administered chronically in doses of 200 to 1000 mg per day for the treatment of hyperthyroidism. Fever, rash, lymphadenopathy, renal damage, agranulocytosis, and fatal aplastic anemia have all been reported as complications of this therapy. Because several alternative therapies for hyperthyroidism are available Perchloracap Capsules are not recommended for treatment of this condition. These adverse effects are dose-related and have not been observed in patients receiving single doses of potassium perchlorate under the conditions described under Dosage and Administration.

#### PRECAUTIONS

##### General

Do not administer Perchloracap capsules that have been subjected to excessive heat and/or moisture as manifested by deformation and/or discoloration of the capsule.

To prevent loss of the desiccated atmosphere, always replace the bottle cap immediately after use.

##### Carcinogenesis, Mutagenesis, Impairment Of Fertility

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential of potassium perchlorate. No adverse effects of potassium perchlorate on fertility have been reported.

#### Pregnancy Category C

Potassium perchlorate has been reported to cause fetal goiter in rabbits and guinea pigs when pregnant females were given daily doses at 18 and 130 times the recommended human dose, respectively. In rabbits, potassium perchlorate was given daily throughout pregnancy at 100 mg/kg for 28 days. In guinea pigs, the mean daily dose was 740 mg/kg during the latter half of pregnancy, with an average treatment duration of 37 days. In both studies, enlargement of the fetal thyroid was observed accompanied by histologic abnormalities characteristic of goiter. There are no adequate and well-controlled studies in pregnant women. Potassium perchlorate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

#### Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when potassium perchlorate is administered to a nursing woman.

#### Pediatric Use

Safety and effectiveness in children have not been established.

#### ADVERSE REACTIONS

Gastric irritation has been reported in therapeutic doses of potassium perchlorate greater than one gram per day. The possibility of temporary local gastric irritation exists with the administration of subtherapeutic doses in capsule form.

#### DOSAGE AND ADMINISTRATION

The usual adult dose is 200 to 400 milligrams of potassium perchlorate administered orally one-half hour to one hour before injection of sodium pertechnetate Tc 99m. The maximum dose should not exceed one gram. Perchloracap should be administered with several ounces of water to prevent gastric irritation.

#### HOW SUPPLIED

Catalog Number 025.

Perchloracap capsules are supplied for oral administration as 200 milligram capsules in bottles of 100. Each opaque capsule is imprinted with NDC 19-N025 to facilitate identification of the dosage form.

#### STORAGE

Keep tightly closed and store in original container at room temperature (below 86<sup>0</sup>F/30<sup>0</sup>C). Avoid high humidity.

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