05/2024

תראקאפ 131 Theracap 131

מרכיבים פעילים:
SODIUM IODIDE (^{131}I) 37 - 5550 MBQ
צורת מינון:
HARD CAPSULE

רופא/ה, רוקח/ת נכבד/ה,
חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון .
העלון עודכן בתאריך אפריל 2024 .

ההתוויה הרשומה לתכשיר בישראל – נוסח חדש:

Radioiodine thyroid therapy is indicated in adults and children for:
• Hyperthyroidism: Treatment of Graves' disease, toxic multinodular goitre or autonomous nodules.
• Treatment of papillary and follicular thyroid carcinoma including metastatic disease.
Sodium iodide (131I) therapy is often combined with surgical intervention and with antithyroid medications.

מקראה לעדכונים המסומנים:
מידע שהוסר - מסומן בקו אדום חוצה ~~XXX~~
תוספת - כתב כחול
תוספת חמרה - כתב כחול -מסומן בצהוב מרקר
מידע שעבר מקום - כתב ירוק
הקלה – כתב כחול - מסומן בירוק מרקר

העדכונים נעשו בסעיפים הבאים בעלון לרופא:

4.1 Therapeutic indications
Radioiodine thyroid therapy is indicated in adults and children for:

- Hyperthyroidism: Treatment of Graves' disease, toxic multinodular goitre or autonomous nodules.
- Treatment of papillary and follicular thyroid carcinoma including metastatic disease.

Sodium iodide (^{131}I) therapy is often combined with surgical intervention and with antithyroid medicinal products.

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4.2 Posology and method of administration

This medicinal product should be administered only by authorized healthcare professionals in designated clinical settings (see section 6.6).

Posology

The activity to be administered is a matter ~~for~~ of clinical judgement. The therapeutic effect is only achieved after several ~~months~~weeks. The activity of the capsule should be determined before use.

Adults

~~For the t~~*Treatment of hyperthyroidism*

In case of failure or impossibility to pursue the medical treatment, radioactive iodide may be administered to treat the hyperthyroidism.

Patients should be rendered euthyroid medically whenever possible before giving radioiodine treatment for hyperthyroidism.

The activity to be administered ~~is usually in the range of 200-800 MBq but repeated treatment may be necessary. The dose required~~ depends on the diagnosis, the size of the gland, thyroid uptake and iodine clearance. It is usually in the range of 200-800 MBq for a patient of average weight (70 kg) but repeated treatment up to a cumulative dose of 5000 MBq may be necessary. Re-treatment after 6-12 months is indicated for persisting hyperthyroidism~~Patients should be rendered euthyroid medically whenever possible before giving radioiodine treatment for hyperthyroidism~~.

The activity to be administered may be defined by fixed dose protocols or may be calculated according to the following equation:

$$A\ (MBq) = \frac{\text{Target dose (Gy)} \times \text{target volume (ml)}}{\text{max. uptake I-131 (\%)} \times \text{effective } T_{1/2} \text{ (days)}} \times K$$

under the following conditions

target dose	is the target absorbed dose in the whole thyroid gland or in an adenoma
target volume	is the volume of the whole thyroid gland (Graves' disease, multifocal or disseminated autonomy)
max. uptake I-131	is the max. uptake of I-131 in the thyroid gland or nodules in % of the administered activity as established in a test dose
effective $T_{1/2}$	is the effective half- life of I-131 in the thyroid gland expressed in days
K	is 24.67

The following target organ doses may be used:

Unifocal autonomy	300 – 400 Gy target organ dose
Multifocal and disseminated Autonomy	150 – 200 Gy target organ dose
Graves' disease	200 Gy target organ dose

In the case of Graves' disease, multifocal or disseminated autonomy, the above mentioned target organ doses are related to the overall volume of the thyroid gland mass, however in the case of unifocal autonomy, the target organ dose is only related to the volume of the adenoma. For recommended doses to target organs, see section 11.

Other dosimetric procedures may also be used including sodium pertechnetate (99mTc) thyroid uptake tests to determine the appropriate target organ dose (Gy).

~~For t~~*Thyroid ablation and treatment of metastases*

The activities to be administered ~~The administered activities~~ following total or sub total thyroidectomy to ablate remaining thyroid tissue are in the range of 1850-3700 MBq. It depends on the remnant size and radioiodine uptake. ~~In subsequent~~For treatment for metastases, administered activity is in the range 3700-11100 MBq.

Special populations

Renal impairment

Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in patients with reduced renal function. The therapeutic use of sodium iodide (131I) in patients with significant renal impairment requires special attention (see section 4.4).

Paediatric population

The use of sodium iodide (131I) in children and adolescents has to be considered carefully, based upon clinical needs and assessing the benefit/risk ratio in this patient group.

In certain cases the activity to be administered in children and adolescents should be determined after performing an individual dosimetry (see section 4.4).

In children and adolescents, treatment of benign thyroid defects with radioactive iodide is possible in justified cases, in particular in case of relapse after the use of antithyroid medicinal products or in case of severe adverse reaction to antithyroid medicinal products (see section 4.4).~~The activity to be administered in children and adolescents should be a fraction of the adult dose calculated from the body weight/surface area methods according to the following equation.~~

~~Paediatric dose (MBq) = Adult dose (MBq) x child weight (kg) / 70 kg~~

~~Paediatric dose (MBq) = Adult dose (MBq) x child surface (m^2) / 1.73 m^2~~

~~Correction factors given for guidance are proposed below.~~

~~Fraction of adult dose~~		
~~3Kg = 0.10~~	~~22Kg = 0.50~~	~~42Kg = 0.78~~
~~4Kg = 0.14~~	~~24Kg = 0.53~~	~~44Kg = 0.80~~
~~6Kg = 0.19~~	~~26Kg = 0.56~~	~~46Kg = 0.82~~
~~8Kg = 0.23~~	~~28Kg = 0.58~~	~~48Kg = 0.85~~
~~10Kg = 0.27~~	~~30Kg = 0.62~~	~~50Kg = 0.88~~
~~12Kg = 0.32~~	~~32Kg = 0.65~~	~~52-54Kg = 0.90~~
~~14Kg = 0.36~~	~~34Kg = 0.68~~	~~56-58Kg = 0.92~~
~~16Kg = 0.40~~	~~36Kg = 0.71~~	~~60-62Kg = 0.96~~
~~18Kg = 0.44~~	~~38Kg = 0.73~~	~~64-66Kg = 0.98~~
~~20Kg = 0.46~~	~~40Kg = 0.76~~	~~68Kg = 0.99~~

~~(Paediatric Task Group, European Association of Nuclear Medicines (EANM))~~

Method of administration

~~The capsule~~Theracap is ~~administered~~ for oral~~ly~~ use. The capsule should be taken ~~together with a drink~~on an empty stomach. ~~It should be swallowed whole.~~

~~In patients with suspected gastrointestinal disease, great care should be taken when administering sodium [^{131}I] iodide capsules.~~ The ~~capsules~~ should be swallowed whole with ~~sufficient fluid~~abundant drink to ensure clear passage into the stomach and upper small intestine. ~~Concomitant use of H_2 antagonists or proton pump inhibitors is advised.~~

In case of administration to children, especially to younger children, it must be ensured that the capsule can be swallowed whole without chewing. It is recommended to give the capsule with mashed food.

For patient preparation, see section 4.4.~~After high doses used e.g. for the treatment of thyroid carcinoma, patients should be encouraged to increase oral fluids to have frequent bladder emptying to reduce bladder radiation~~.

למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות , וניתן לקבלו מודפס על ידי פניה לבעל הרישום אלדן ציוד אלקטרוני בע"מ, בנין ניאופרם, רח' השילוח 6 ת.ד 7641 פתח תקוה 4917001, טלפון: 03-9371111, פקס: 03-9371100.

בברכה,

עוז וולך

רוקח ממונה