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CERETEC / סרטק
Powder for Solution for Injection

רופא/ה, רוקח/ת נכבד/ה,
חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון . העלון עודכן בתאריך מרץ 2025 ובולל נוסח מחודש לפרקי התוויה ומשטר המינון.

התוויה מאושרת לתכשיר בישראל:

This medicinal product is for diagnostic use only.
After reconstitution with Sodium Pertechnetate (99mTc) Injection, the solution of technetium (99mTc) exametazime is indicated for:
Neurology
- Technetium (99mTc) Exametazime Injection is indicated for use with single photon emission tomography (SPECT). In brain perfusion SPECT, the diagnostic target is detection of abnormalities of regional cerebral blood flow, including: Evaluation of patients with cerebrovascular disease (specifically acute stroke, chronic ischaemia and transient ischaemic attack);
- Presurgical lateralisation and localisation of ictal and interictal epileptogenic foci;
-Evaluation of cerebrovascular reserve in certain conditions
- Evaluation of patients with suspected dementia (specifically Alzheimer's disease and frontotemporal dementia, vascular dementia(;
- Adjuvant technique in the diagnosis of brain death

Infectious or inflammatory diseases
Technetium (99mTc) Exametazime Injection is also indicated for in vitro technetium-99m leucocyte labelling the labelled leucocytes subsequently being re-injected and scintigraphy carried out to image the sites of localisation. This procedure may be used in the detection of sites of focal infection (e.g. abdominal abscess, bone and prosthetic joint infection), in the investigation of pyrexia of unknown origin an the evaluation of inflammatory conditions not associated with infection such as inflammatory bowel disease.

בהודעה זו מתוארים העדכונים העיקריים בעלון לרופא, בעלון קיימים עדכונים נוספים.
<u>מקראה לעדכונים המסומנים:</u>
מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
תוספת – כתב **כחול**

4.1 Therapeutic Indications
This medicinal product is for diagnostic use only.

After reconstitution with Sodium Pertechnetate (^{99m}Tc) Injection, the solution of technetium (^{99m}Tc) exametazime ~~product~~ is indicated ~~in adults~~ for:

Neurology ~~regional cerebral blood flow scintigraphy leucocytes labelling:~~
- ~~—~~Technetium (^{99m}Tc) Exametazime Injection is indicated for use with single photon emission tomography (SPECT). In brain perfusion SPECT ~~scintigraphy. The product is to be used for~~ the ~~diagnosis~~ diagnostic target is detection of abnormalities of regional cerebral blood flow, including:
- Evaluation of patients with cerebrovascular disease (specifically acute stroke, chronic ischaemia and transient ischaemic attack);
- Presurgical lateralisation and localisation of ictal and interictal epileptogenic foci;
- Evaluation of cerebrovascular reserve in certain conditions
- Evaluation of patients with suspected dementia (specifically Alzheimer's disease and

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frontotemporal dementia, vascular dementia);

- Adjuvant technique in the diagnosis of brain death~~such as those occurring following stroke and other cerebrovascular disease, epilepsy, Alzheimer's Disease and other forms of dementia, transient ischaemic attack, migraine and tumours of the brain.~~

Infectious or inflammatory diseases

Technetium (^{99m}Tc) Exametazime Injection is also indicated for *in vitro* technetium-99m leucocyte labelling, the labelled leucocytes subsequently being re-injected and scintigraphy carried out to image the sites of localisation. This procedure may be used in the detection of sites of focal infection (e.g. abdominal abscess, bone and prosthetic joint infection), in the investigation of pyrexia of unknown origin and in the evaluation of inflammatory conditions not associated with infection such as inflammatory bowel disease.

4.2 Posology and method of administration

The route of administration is direct intravenous injection for brain scintigraphy studies and intravenous injection of labelled leucocytes post labelling *in vitro*.

Posology

Adults ~~and the elderly population~~

- ~~(i) f~~For brain scintigraphy~~:~~ ~~350~~555-~~500MBq~~1110MBq
- ~~(ii) f~~For *in vivo* localisation of technetium-99m-labelled leucocytes~~:~~ ~~200MBq~~185-370MBq

~~- Normally a once-only diagnostic procedure~~

Paediatric population

There are no clinical safety studies completed in children and adolescents. Safety and effectiveness in paediatric patients less than 2 years of age have not been established. Use of this product in paediatric patients 2 years of age and older is extrapolated from clinical experience and data on clinical effectiveness in adults.

The use in children and adolescents must be considered carefully, based upon clinical needs and following assessment the risk/benefit ratio in this patient group by a physician experienced in paediatric nuclear medicine.

The activities to be administered to children and adolescents may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) Paediatric Dosage Card (Version 5.7.2016) for a given patient weight as tabulated below. National diagnostic reference levels should not be exceeded.

—For brain scintigraphy

Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)
3	100.0	22	274.0	42	473.5
4	100.0	24	295.8	44	495.7
6	100.0	26	318.1	46	518.0
8	110.9	28	333.1	48	533.0
10	140.4	30	355.3	50	554.8
12	162.7	32	377.6	52-54	584.8
14	184.9	34	399.9	56-58	621.6
16	207.2	36	414.4	60-62	658.4
18	229.5	38	436.7	64-66	695.7
20	251.7	40	458.9	68	725.2

For *in-vivo* localisation of technetium-99m-labelled leukocytes

Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)
3	40.0	22	185.2	42	319.9
4	40.0	24	199.9	44	335.0
6	59.9	26	214.9	46	350.0
8	74.9	28	225.1	48	360.2
10	94.9	30	240.1	50	374.9
12	109.9	32	255.2	52-54	395.2
14	125.0	34	270.2	56-58	420.0
16	140.0	36	280.0	60-62	444.9
18	155.1	38	295.1	64-66	470.1
20	170.1	40	310.1	68	490.0

~~Technetium 99m exametazime and technetium 99m labelled leucocytes are not recommended for administration to children.~~

Normally a once-only diagnostic procedure

4.4 Special warnings and precautions for use

(...)

Paediatric population

For information on the use in ~~Paediatric~~ paediatric population, see section 4.2. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section ~~11~~ 7).

4.8 Undesirable effects

The frequencies of undesirable effects are defined as follows:

Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

Congenital and familial/genetic disorders Not known	Hereditary defects[1].
Neoplasms benign and malignant (including cysts and polyps) Not known	Cancer induction[1].
Immune system disorders Not known	Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus
Re-injected Ceretec labelled leukocytes only Not known	Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus, anaphylactoid reaction or anaphylactoid shock
Nervous system disorders Not known	Headache, dizziness, paraesthesia
Vascular disorders Not known	Flushing
Gastrointestinal disorders Not known	Nausea, vomiting
General disorders and administration site conditions Not known	Asthenic conditions (e.g., malaise, fatigue)

[1] Linked with ionising radiation

~~**Immune system disorders**~~
~~Not known: Hypersensitivity including rash, erythema, urticaria, angioedema, pruritus. Re injected Ceretec labelled leukocytes only:~~
~~Not known: Hypersensitivity including rash, erythema, urticaria, angioedema, pruritus, anaphylactoid reaction or anaphylactoid shock.~~

~~**Nervous system disorders**~~
~~Not known: Headache, dizziness, paraesthesia~~

~~**Vascular disorders**~~
~~Not known: Flushing~~

~~**Gastrointestinal disorders**~~
~~Not known: Nausea, vomiting~~

~~**General disorders and administration site conditions**~~
~~Not known: Asthenic conditions (e.g., malaise, fatigue)~~
Exposure to ionising radiation is linked with cancer induction and a potential for ~~developing~~ development of hereditary defects. As the effective dose
resulting from the administration of a (maximal recommended) activity of 1110 MBq for an adult weighing 70 kg is about 10.3 mSv~~is 5.2 mSv when the maximal recommended activity of 555 MBq is administered~~, these adverse events are expected to occur with a low probability.

7. DOSIMETRY

Technetium (^{99m}Tc) is produced by means of a (^{99}Mo/^{99m}Tc) generator and decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6.02 hours to technetium (^{99}Tc) which, in view of its long half-life of 2.13 x 10^5 years can be regarded as quasi stable.

Brain scintigraphy

The ~~data listed~~table below ~~are from~~shows the dosimetry according to ICRP publication 128 ~~(~~(International Commission o~~n~~f Radiological Protection, – Radiation Dose to Patients from Radiopharmaceuticals: A Compendium of Current Information Related to Frequently Used Substances, Ann ICRP 2015).

~~(1) Brain scintigraphy~~
~~The table below shows the dosimetry as calculated according to the Publication 62 of the ICRP (International Commission on Radiological Protection in Biomedical Research, Pergamon Press 1991) following administration of technetium ^{99m}Tc-exametazime to adults.~~

Organ	Absorbed dose per unit activity administered (mGy/MBq) Adult
Adrenals	5.3E-03
Bladder	2.3E-02
Bone surfaces	5.1E-03
Brain	6.8E-03
Breast	2.0E-03
Gall bladder	1.8E-02
GI tract	
Stomach	6.4E-03
SI	1.2E-02
ULI	1.8E-02
LLI	1.5E-02
Heart	3.7E-03
Kidneys	3.4E-02
Liver	8.6E-03
Lungs	1.1E-02
Muscles	2.8E-03
Oesophagus	2.6E-03
Ovaries	6.6E-03
Pancreas	5.1E-03
Red marrow	3.4E-03
Skin	1.6E-03
Spleen	4.3E-03
Testes	2.4E-03
Thymus	2.6E-03
Thyroid	2.6E-02
Uterus	6.6E-03
Remaining organs	3.2E-03
Effective dose (mSv/MBq)	**9.3E-03**

Effective Dose is 4.7 mSv/500 MBq (70kg individual)

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Organ	Absorbed dose per unit activity administered (mGy/MBq)					
	Adult	15 years	10 years	5 years	1 year	Newborn
Adrenals	0.0053	0.0067	0.0099	0.014	0.024	0.066
Bone surfaces	0.0051	0.0064	0.0094	0.014	0.024	0.073
Brain	0.0068	0.011	0.016	0.021	0.037	0.084
Breast	0.0020	0.0024	0.0037	0.0056	0.0095	0.034
Gallbladder wall	0.018	0.021	0.028	0.048	0.14	0.32
Gastrointestinal tract						
——Stomach wall	0.0064	0.0085	0.012	0.019	0.036	0.14
–Small intestine wall	0.012	0.015	0.024	0.036	0.065	0.21
–Colon wall	0.17	0.022	0.035	0.055	0.10	0.29
(Upper large intestine wall	0.018	0.024	0.038	0.060	0.11	0.31
(Lower large intestine wall	0.015	0.019	0.031	0.048	0.090	0.27
Heart wall	0.0037	0.0047	0.0067	0.0097	0.016	0.050
Kidneys	0.034	0.041	0.057	0.081	0.14	0.36
Liver	0.0086	0.011	0.016	0.023	0.040	0.092
Lungs	0.011	0.016	0.022	0.034	0.063	0.17
Muscles	0.0028	0.0035	0.0050	0.0073	0.013	0.045
Oesophagus	0.0026	0.0033	0.0047	0.0069	0.011	0.041
Ovaries	0.0066	0.0083	0.012	0.017	0.027	0.081
Pancreas	0.0051	0.0065	0.0097	0.014	0.023	0.069
Red marrow	0.0034	0.0041	0.0059	0.0080	0.014	0.042
Skin	0.0016	0.0019	0.0029	0.0045	0.0083	0.032
Spleen	0.0043	0.0054	0.0082	0.012	0.020	0.059
Testes	0.0024	0.0030	0.0044	0.0061	0.011	0.039
Thymus	0.0026	0.0033	0.0047	0.0069	0.011	0.041
Thyroid	0.026	0.042	0.063	0.14	0.26	0.37
Urinary bladder wall	0.023	0.028	0.033	0.033	0.056	0.15
Uterus	0.0066	0.0081	0.012	0.015	0.025	0.075
Remaining organs	0.0032	0.0040	0.0060	0.0092	0.017	0.053
Effective dose (mSv/MBq)	0.0093	0.011	0.017	0.027	0.049	0.12

The effective dose resulting from the administration of a (maximal recommended) activity of 1110 -MBq for an adult weighing 70 kg is about 10.3 mSv ~~and is calculated according to the following assumptions:~~

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~~Maximal recommended activity (MBq) x effective dose (mSv/MBq):1110 MBq x 9.3mSv/MBq = 10.3mSv~~

For an administered activity of 740 MBq the typical radiation dose to the target organ (brain) is 5.0 mGy and the typical radiation dose/doses to the critical organ (kidneys) is 25.2 mGy.

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,

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