הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך: 01.07.13

שם תכשיר באנגלית ומספר הרישום: DATSCAN 74 MBQ/ML

שם בעל הרישום: ELDAN ELECTRONIC INSTRUMENT

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
This medicinal product is for diagnostic use only. DaTSCAN is indicated for detecting loss of functional dopaminergic neuron terminals in the striatum: • In **adult** patients with clinically uncertain Parkinsonian Syndromes, **for example those with early symptoms**, in order to help differentiate Essential Tremor from Parkinsonian Syndromes related to idiopathic Parkinson's Disease, Multiple System Atrophy and Progressive Supranuclear Palsy. DaTSCAN is unable to discriminate between Parkinson's Disease, Multiple System Atrophy and Progressive Supranuclear Palsy. • **In adult patients, to** help differentiate probable dementia with Lewy bodies from Alzheimer's disease. DaTSCAN is unable to discriminate between dementia with Lewy bodies and Parkinson's disease dementia.	~~Therapoitic group; other dopaminergic agents~~ This medicinal product is for diagnostic use only. DaTSCAN is indicated for detecting loss of functional dopaminergic neuron terminals in the striatum: • In patients with clinically uncertain Parkinsonian Syndromes, in order to help differentiate Essential Tremor from Parkinsonian Syndromes related to idiopathic Parkinson's Disease, Multiple System Atrophy and Progressive Supranuclear Palsy. DaTSCAN is unable to discriminate between Parkinson's Disease, Multiple System Atrophy and Progressive Supranuclear Palsy. • ~~T~~o help differentiate probable dementia with Lewy bodies from Alzheimer's disease. DaTSCAN is unable to discriminate between dementia with Lewy bodies and Parkinson's disease dementia.	**4.1 Therapeutic indications**
Prior to administration appropriate resuscitation equipment should be available. DaTSCAN should only be used in **adult** patients referred by physicians experienced in the management of movement disorders and/or dementia. **DaTSCAN** should only be used by qualified personnel with the appropriate government authorisation for the use and manipulation of radionuclides within a designated clinical setting. **Posology** Clinical efficacy has been demonstrated across the range 111**to** 185 MBq. Do not exceed 185 MBq and do not use when the activity is below 110 MBq.	DaTSCAN should only be used in patients referred by physicians experienced in the management of movement disorders and/or dementia. ~~Radiopharmaceutical agents~~ should only be used by qualified personnel with the appropriate government authorisation for the use and manipulation of radionuclides within a designated clinical setting.	**4.2 Posology and method of administration**

	~~DaTSCAN is a 5% (v/v) ethanolic solution for intravenous injection and should be used without dilution.~~ Clinical efficacy has been demonstrated across the range 111-185 MBq. Do not exceed 185 MBq and do not use when the activity is below 110 MBq. ~~In the event of overdosage, refer to section 4.9.~~ ~~To minimise the potential for pain at the injection site during administration, a slow intravenous injection (not less than 15 – 20 seconds) via an arm vein is recommended.~~	
Patients must undergo appropriate thyroid blocking treatment prior to injection to minimise thyroid uptake of radioactive iodine, for example by oral administration of approximately 120 mg potassium iodide 1 **to** 4 hours prior to injection of DaTSCAN. ***Special Populations*** ***Renal and hepatic impairment*** **Formal studies have not been carried out in patients with significant renal or hepatic impairment. No data are available (see section 4.4).** ***Paediatric populations*** **The safety and efficacy of DaTSCAN in children aged 0 to 18 years has not been established. No data are available.** **Method of Administration** **For intravenous use.** **DaTSCAN should be used without dilution.** **To minimise the potential for pain at the injection site during administration, a slow intravenous injection (not less than 15 to 20 secinds) via an arm vein is recommended.** SPECT imaging should take place between three and six hours post-injection. Images should be acquired using a gamma camera fitted with a high-resolution collimator and calibrated using the 159keV photopeak and a ± 10% energy window. Angular sampling should preferably be not less than 120 views over 360 degrees. For high resolution collimators the radius of rotation should be consistent and set as small as possible (typically 11-15 cm). Experimental studies with a striatal phantom, suggest that optimal images are obtained with matrix size and zoom factors selected to give a pixel size of 3.5 – 4.5 mm for those systems currently in use. A minimum of 500k counts should be collected for optimal images. Normal images are characterised by two	Patients must undergo appropriate thyroid blocking treatment prior to injection to minimise thyroid uptake of radioactive iodine, for example by oral administration of approximately 120 mg potassium iodide 1-4 hours prior to injection ~~and again 12-24 hours post-injection~~ of DaTSCAN. SPECT imaging should take place between three and six hours post-injection. Images should be acquired using a gamma camera fitted with a high-resolution collimator and calibrated using the 159keV photopeak and a ± 10% energy window. Angular sampling should preferably be not less than 120 views over 360 degrees. For high resolution collimators the radius of rotation should be consistent and set as small as possible (typically 11-15 cm). Experimental studies with a striatal phantom, suggest that optimal images are obtained with matrix size and zoom factors selected to give a pixel size of 3.5 – 4.5 mm for those systems currently in use. A minimum of 500k counts should be collected for optimal images. Normal images are characterised by two symmetrical	

symmetrical crescent-shaped areas of equal intensity. Abnormal images are either asymmetric or symmetric with unequal intensity and/or loss of crescent.	crescent-shaped areas of equal intensity. Abnormal images are either asymmetric or symmetric with unequal intensity and/or loss of crescent. ~~DaTSCAN is not recommended for use in children or adolescents due to a lack of data on safety and efficacy.~~	
If hypersensitivity reactions occur, the administration of the medicinal product must be discontinued immediately and, if necessary, intravenous treatment intiated. Resuscitative medicinal products and equipment (e.g endotracheal tube and ventilator) have to be readily available. This radiopharmaceutical may be received, used and administered only by authorised persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and the appropriate licences of the local competent official organisations. **For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result.** Formal studies have not been carried out in patients with significant renal or hepatic impairment. In the absence of data, DaTSCAN is not recommended in cases of moderate to severe renal or hepatic impairment. This medicinal product contains **39.5 g/l** (5% volume) ethanol (alcohol), up to 197 mg per dose, equivalent to 5ml beer **or** 2 ml wine. Harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver disease or epilepsy.	This radiopharmaceutical may be received, used and administered only by authorised persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and the appropriate licences of the local competent official organisations. Formal studies have not been carried out in patients with significant renal or hepatic impairment. In the absence of data, DaTSCAN is not recommended in cases of moderate to severe renal or hepatic impairment. This medicinal product contains (5% volume) ethanol (alcohol), up to 197 mg per dose, equivalent to 5ml beer~~,~~ 2 ml wine. Harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver disease or epilepsy.	**4.4 Special warnings and special precautions for use**
Summary of the safety profile No serious adverse reactions related to DaTSCAN administration have been reported. **Tabulated summary of adverse reactions** **The frequencies of adverse reactions are defined as follows:** **Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <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). Within**	No serious adverse reactions related to DaTSCAN administration have been reported. ~~The following common side effects are recognised for DaTSCAN:~~ *Metabolism and nutrition disorders* Appetite increased *Nervous system disorders*	**4.8 Undesirable effects**

each frequency grouping, undesirable effects are presented in order of decreasing seriousness. **Immune system disorders** **Not known: Hypersensitivity** **Metabolism and nutrition disorders** **Uncommon:** Appetite increased **Nervous system disorders** **Common**: Headache **Uncommon: Dizziness,** formication (paraesthesia), **dysgeusia** **Ear and labyrinth disorders** **Uncommon:** Vertigo **Gastrointestinal disorders** **Uncommon: Nausea, dry mouth** **General disorders and administration site conditions** **Uncommon:** Injection site pain (intense pain following administration into small veins). Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects**. As the effective dose is 4.35 mSv when the maximal recommended activity of 185 MBq is administered these adverse events are expected to occur with a low probability.**	Headache formication (paraesthesia) *Ear and labyrinth disorders* Vertigo ~~The following uncommon side effects are recognized for DaTSCAN:~~ *General disorders and administration site conditions* Injection site pain (intense pain following administration into small veins) ~~For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result.~~ Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. ~~For diagnostic nuclear medicine investigations, the current evidence suggests that these adverse events will occur with negligible frequency because of the low radiation dose incurred.~~	

Non-clinical data for ioflupane reveal no special hazard for humas based on conventional studies of safety pharmacology, single and repeated dose toxicity and genotoxicity. Studies on reproductive toxicity **and** to assess the carcinogenic potential of ioflupane have not been performed.	~~Acute toxicity studies employing ioflupane at dosage levels of 0.06 mg/kg, in excess of 6,500 times the maximum human (70 kg) single dose on a bodyweight basis, failed to reveal any mortality or signs of systemic toxicity in rats or rabbits. In 14 day repeat dose studies no evidence of toxicity was observed in rats or rabbits following daily doses of 0.6 mg/kg ioflupane, more than 65,000 times the maximum human (70 kg) single dose on a bodyweight basis. Behavioural effects due to pharmacological activity were observed in these studies.~~ Studies on reproductive toxicity ~~have not been conducted. Ioflupane showed no evidence of mutagenic potential in *in vitro* or *in vivo* mutagenicity studies. Studies~~ to assess the carcinogenic potential of ioflupane have not been performed.	**5.3 Preclinical safety data**