PRESCRIBING INFORMATION DaTSCAN™ ioflupane (^{123}I) 74 MBq/ml solution for injection
Please refer to full Summary of Product Characteristics (SPC) before prescribing. Further information available on request.

PRESENTATION
Single dose vials containing 185 MBq or 370 MBq ioflupane (^{123}I) at reference time.

INDICATIONS
Detecting loss of functional dopaminergic neuron terminals in the striatum.
i) 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 (PD), Multiple System Atrophy (MSA) and Progressive Supranuclear Palsy (PSP). DaTSCAN is unable to discriminate between PD, MSA and PSP.
ii) in adult patients to help differentiate probable dementia with Lewy bodies (DLB) from Alzheimer's disease. DaTSCAN is unable to discriminate between DLB and Parkinson's Disease dementia.

DOSAGE AND METHOD OF ADMINISTRATION
Prior to administration appropriate resuscitation equipment should be available. For use in patients referred by physicians experienced in the management of movement disorders/dementia. Clinical efficiency has been demonstrated across the range of 111-185 MBq; do not use outside this range. Appropriate thyroid blocking treatment must be given prior to injection of DaTSCAN. The safety and efficacy of DaTSCAN in children 0 to 18 years has not been established.
No data are available in patients with significant renal or hepatic impairment. DaTSCAN should be used without dilution. Slow intravenous injection (15-20 seconds) via an arm vein is recommended. SPECT imaging should take place 3-6 hours after injection of DaTSCAN.
DaTSCAN images are interpreted visually, based upon the appearance of the striata. As an adjunct, visual interpretation may be assisted by semi-quantitative assessment. Semi-quantification should only be used an adjunct to visual assessment following the precautions described in the Summary of Product characteristics. Final assessment should always consider both visual appearance and semi-quantitative results.

CONTRAINDICATIONS
Pregnancy and hypersensitivity to the active substance or any of the excipients.

WARNINGS AND PRECAUTIONS
If hypersensitivity reactions occur, the administration of the medicinal product must be discontinued immediately and, if necessary, intravenous treatment initiated. 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. The patient should be well hydrated before and after the examination and urged to void as often as possible during the first 48 hours after the procedure in order to minimise radiation exposure. DaTSCAN is not recommended in cases of moderate to severe renal or hepatic impairment. Contains 39.5 g/l (5% volume) ethanol, up to 197mg per dose, harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver disease or epilepsy.

INTERACTIONS
Consider current medication. Medicines that bind to the dopamine transporter with high affinity may interfere with diagnosis; these include amfetamine, bupropion, cocaine, codeine, dexamfetamine, methylphenidate, modafinil, and phentermine. Selective serotonin reuptake inhibitors, such as sertraline, may increase or decrease ioflupane binding to the dopamine transporter. Medicines shown during clinical trials not to interfere with DaTSCAN imaging include amantadine, trihexyphenidyl, budipine, levodopa, metoprolol, primidone, propranolol and selegiline. Dopamine agonists and antagonists acting on the postsynaptic dopamine receptors are not expected to interfere with DaTSCAN imaging and can therefore be continued if desired. In animal studies pergolide does not interfere with DaTSCAN imaging.

PREGNANCY AND LACTATION
Contraindicated in pregnancy. Information should be sought about pregnancy from women of child bearing potential. A woman who has missed her period should be assumed to be pregnant. If uncertain, radiation exposure should be the minimum needed for satisfactory imaging. Consider alternative techniques. If administration to a breast feeding woman is necessary, substitute formula feeding for breast feeding for 3 days.

UNDESIRABLE EFFECTS
The following undesirable effects are recognised for DaTSCAN: Common side effects include headache. Uncommon side effects include vertigo, increased appetite, formication, dizziness, dysgeusia, nausea and dry mouth. Intense pain or burning sensation on injection has been reported uncommonly following administration into small veins. Hypersensitivity occurs with unknown frequency, as well as erythema, pruritus, rash, urticaria, hyperhidrosis, dyspnea, vomiting, decreased blood pressure and feeling hot. Exposure to ionising radiation is linked with cancer induction and a potential for hereditary defects. Because of the low radiation dose incurred these adverse events are expected to occur with a low probability.

DOSIMETRY
Effective dose from 185 MBq is 4.63 mSv.

OVERDOSE
Encourage frequent micturition and defecation.

MARKETING AUTHORISATION HOLDER
GE Healthcare B.V., De Rondom 8, 5612 AP, Eindhoven, The Netherlands

CLASSIFICATION FOR SUPPLY
Subject to medical prescription.

MARKETING AUTHORISATION NUMBERS
EU/1/00/135/001 (2.5ml) and EU/1/00/135/002 (5.0ml).

DATE OF REVISION OF TEXT
Date of revision of text: (June 2024), based on SmPC dated (May 2024).

UK PRICE
£525.00/185MBq

Adverse events should be reported.
Reporting forms and information can be found at http://www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to GE HealthCare at gpv.drugsafety@gehealthcare.com.