DaTSCAN™
IOFLUPANE (^{123}I)

Patient preparation:
Potential Drug Interference with DaTSCAN

Drugs that bind to the dopamine transporter with high affinity may interfere with the DaTSCAN image. Whether discontinuation of these drugs prior to DaTSCAN administration may minimize the interference with a DaTSCAN image has not been determined by controlled in vivo or in vitro studies. The impact of dopamine agonists and antagonists on DaTSCAN imaging results has not been established.

The benefits and risks of stopping a medication that may interfere with the reliability of the information in a DaTSCAN image is a medical consideration that should be made on an individual basis.

The decision to withhold or stop any potentially interacting medication should be determined by the patient's physician(s), in consultation with a pharmacist, after obtaining a thorough medication history.

The data below are compiled from approved labelling and published literature to provide some assistance in deciding how to handle concomitant medications prior to administration of DaTSCAN for single-photon emission computed tomography (SPECT) imaging.[1,2]

The following drugs should not significantly interfere with ioflupane binding and do not need to be stopped:[2,3]

- Cholinesterase inhibitors and neuroleptics
- Anti-parkinsonian drugs (e.g., L-dihydroxyphenylalanine, dopamine agonists, monoamine oxidase-B inhibitors, N-methyl-D-aspartate receptor blockers, amantadine, and catechol-O-methyltransferase inhibitors in standard dosages)
- Selective serotonin reuptake inhibitors (e.g. Sertraline) may increase binding to the DaT somewhat but should not interfere with visual interpretation

Medication that may interfere with Ioflupane binding and therefore should be stopped for at least 5 half-lives prior to scan[1,4]	**5 half-lives are approximately equal to**
Ephedrine, ketamine, isoflurane	1 days
Cocaine, methylphenidate	2 days
Methamphetamine, mazindol, modafinil	3 days
Benzatropine, fentanyl	5 days
Amfetamine, dexamphetamine	7 days
Buproprion	8 days
Phentermine	14 days

References:
1. Darcourt *et al.* Eur J Nucl Med Mol Imaging 2010; 37: 443–50.
2. Booij J *et al.* Eur J Nucl Med Mol Imaging 2008; 35(2):424-38.
3. DaTSCAN Summary of Product Characteristics, January 2021.
4. Kagi *et al.* J Neurol Neurosurg Psychiatry 2010; 81: 5–12. doi:10.1136/jnnp.2008.157370

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. 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, benzatropine, buproprion, cocaine, mazindol, methylphenidate, phentermine and sertraline. 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

16 March 2021

UK PRICE

£525.00/185MBq

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/.
Adverse events should also be reported to GE Healthcare at Gpv.drugsafety@ge.com

GE Healthcare Limited, Pollards Wood, Nightingales Lane, Chalfont St Giles, Buckinghamshire, England HP8 4SP

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