

^{123}I -FP-CIT (^{123}I -ioflupane)

DATrace-123

An Effective Solution for The Diagnosis of Parkinsonian Syndromes
DATrace-123 is a solution for injection that contains the active substance ^{123}I -ioflupane (^{123}I -FP-CIT)

SPECT Dopamin Transporter Imaging Agent



SAMYOUNG UNITECH



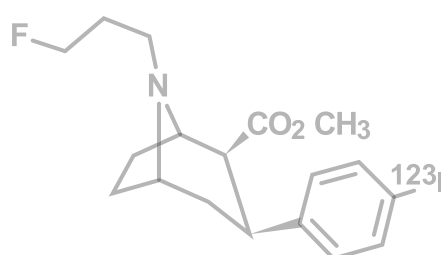
Product Summary

> Product Name

DATrace-123 Injection

> Active Ingredient

N-(3-Fluoropropyl)-2 β -carbomethoxy-3 β -(4-[¹²³I]iodophenyl)nortropane (¹²³I-FP-CIT, ¹²³I-ioflupane)



> Action Mechanism

DATrace-123 is used as a radiopharmaceutical for the SPECT imaging of Dopamine Transporters (located at the end of Dopaminergic neurons) and, to a lesser extent, Serotonin Transporters due to its excellent ability to combine with both of these compounds.

> Clinical Applications

The clinical applications of DATrace-123 using SPECT are as follows:

- Differential diagnosis of Parkinson's Disease¹ with Nigrostriatal Dopaminergic Neuron damage and Essential Tremor
- Differential diagnosis of Parkinson's Disease with Dopaminergic Neuron damage and Parkinson's Disease² without other Dopaminergic Neuron damage
- Differential diagnosis of Dementia with Lewy bodies and Alzheimer's Disease
- Early diagnosis and progression of Parkinson's Disease and evaluation of therapeutic effects

¹ Parkinson's disease, Multiple System Atrophy, progressive supranuclear palsy, etc.

² Drug-induced, Psychogenic, Vascular, Toxin, Inflammatory, etc.

> Other Usage

DATrace-123 can be used for SPECT imaging studies of Dopamine and Serotonin Transporters in Degenerative Neuronal Diseases and other mental diseases.

> Usage/ Capacity

- DATrace-123 is supplied as a finished radiopharmaceutical (injection solution) that can be injected directly into patients without modifications.
- The recommended dose of DATrace-123 for human SPECT imaging is 111-185MBq (3-5mCi) injected directly into a vein.
- To prevent possible pain near the injection area, inject slowly over a period of 15 to 20 seconds into a vein in the upper arm.
- 3 to 6 hours after the DATrace-123 injection, a brain SPECT image can be acquired.
- Visually inspect striatum (Caudate nucleus and integument) intake dispersion of DATrace-123 using reconstructed brain tomography with attenuation correction. Alternatively, perform semi-quantitative inspection by calculating the intake ratio³of specific and aspecific (generally referring to Occipital Lobe Cortex) binding of striatum.
- Take Lugol's solution⁴(comparable to iodide 100mg) once orally 30 to 60 minutes before injecting DATrace-123 or take 200-400mg of potassium perchlorate⁵ once orally so as to reduce thyroid intake of iodine. A small amount of radiation may be detected even if thyroid is blocked.

³ Calculate(Average radiation of striatum ROI (or VIO) – Average radiation of Occipital Lobe Cortex ROI (or VOI) and it is applicable to $V3 = f2B_{max}/K_D = C_3/ C_2 = k_3/k_4 = DVR - 1$

⁴ Iodide 25.3g/L(0.199 mol/L) is sometimes contained in Lugol's solution used by many hospitals. In this case, dilute 4mL of Lugol's solution with either orange juice or water and take orally.

⁵ Potassium perchlorate is not domestically available.

> Drug Interaction

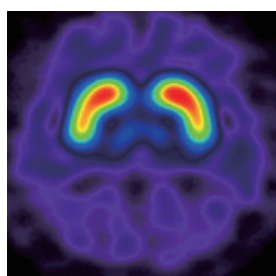
1. Anti-Parkinson's disease drugs (L-DOPA, Dopamine agonist drug, MAO B antagonist drug, NMDA receptor blocker, Amantadine, COMT Antagonist drug) have no effect on the ability of DATrace-123 to combine with Dopamine Transporters. Therefore, drug administration is not required for DATrace-123 SPECT.
2. Cholinesterase antagonist drugs and anti-psychotics have no effect on the ability of DATrace-123 to combine with Dopamine Transporters.
3. SSRI may increase, to some extent, the ability of DATrace-123 to combine with Dopamine Transporters. However, there is no effect on visual imaging inspection.
4. Cocaine, Amphetamines and Methylphenidate decrease the ability of DATrace-123 to combine with Dopamine Transporters.

> References

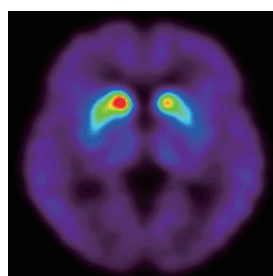
1. Djang DS, Janssen MJ, Bohnen N, Booij J, Henderson TA, Herholz K, Minoshima S, Rowe CC, Sabri O, Seibyl J, Van Berckel BN, Wanner M. SNM practice guidelines for dopamine transporter imaging with ¹²³I-ioflupane SPECT version 1.0. J Nucl Med. 2012;53(1):154-163.
2. Darcourt J, Booij J, Tatsch K, Varrone A, Vander Borgh T, Kapucu OL, Någren K, Nobili F, Walker Z, Van Laere K. EANM procedure guidelines for brain neurotransmission SPECT using ¹²³I-labelled dopamine transporter ligands, version 2. Eur J Nucl Med Mol Imaging. 2010;37(2):443-450.

DATrace-123 Features

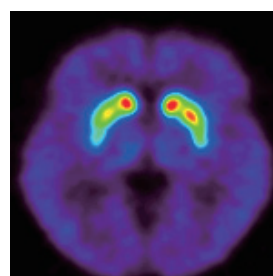
- DATrace-123 and Dopamine Transporter SPECTs which use DATrace-123 have been recognized for their effectiveness and stability by the Korea Food & Drug Administration and Center for New Health Technology Assessment.
- DATrace-123 is comparable to DaTscan™ (Dopamine Transporter SPECT Imaging Radiopharmaceutical) which is sold across Europe and the United States.
- The combination of DATrace-123 with Dopamine Transporter striatum forms a sustained equilibrium, resulting in superb Dopamine Transporter imaging accuracy.
- DATrace-123 is supplied as a finished radiopharmaceutical (injection solution) that can be injected directly into patients without modifications.
- DATrace-123 has a relatively long half-life (13.2 hours) allowing for extensive distribution even to remote hospitals. Furthermore, there is no restriction on the number of patients who can qualify for a one-day exam.
- Samyoung Unitech employs a wide range of logistics partners and methods which help ensure quick and reliable transportation to all of our customers.



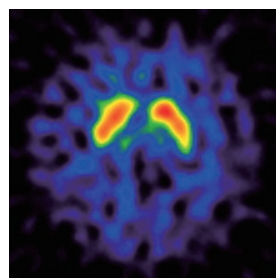
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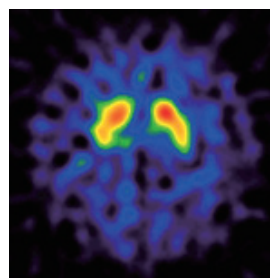
PD



MSA



ET



DIP

SAMYOUNG UNITECH contributes to the bright and healthy future world with innovative and eco-friendly technologies, producing and supplying radiopharmaceuticals for human health

