

## DATSCAN

Active ingredient and strength:  
IOFLUPANE 74 MBQ/ML

חומר פעיל וכמותו:  
איופלופאין 74 מגה בקרלמ"ל

רופא/ה, רוקח/ת נכבד/ה,

- העלון לרופא של המוצר עודכן בנובמבר 2021.
- **בהודעה זו מתוארים רק השינויים העיקריים המהווים החמרה או תוספת מידע.**
- טקסט שנוסף מופיע על רקע אפור, טקסט שנמחק מופיע עם קו חוצה על רקע אפור.

### להלן נוסח ההתוויה המאושר לתכשיר:

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

### העדכונים העיקריים בעלון לרופא נעשו בסעיפים הבאים:

#### 4.2 Posology and method of administration

(...)

##### *Image acquisition*

SPECT imaging should take place between three and six hours post-injection. Images should be acquired using gamma camera fitted with a high-resolution collimator and calibrated using the 159keV photopeak and a  $\pm 10\%$  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 (see section 4.4). ~~Normal images are characterised by two symmetrical crescent-shaped areas of equal intensity. Abnormal images are either asymmetric or symmetric with unequal intensity and/or loss of crescent~~

#### 4.4 Special warnings and special precautions for use

(...)

##### Interpretation of DaTSCAN Images

DaTSCAN images are interpreted visually, based upon the appearance of the striata.

Optimum presentation of the reconstructed images for visual interpretation is transaxial slices parallel to the anterior commissure-posterior commissure (AC-PC) line. Determination of whether an image is normal or abnormal is made by assessing the extent (as indicated by shape) and intensity (in relation to the background) of the striatal signal.



Normal images are characterised by two symmetrical crescent-shaped areas of equal intensity.

Abnormal images are either asymmetric or symmetric with unequal or reduced intensity and/or loss of crescent.

As an adjunct, visual interpretation may be assisted by semi-quantitative assessment using CE-marked software, where DaTSCAN uptake in the striatum is compared with uptake in a reference region and ratios are compared against an age adjusted healthy subjects' database. The evaluation of ratios, such as the left/right striatum DaTSCAN uptake (symmetry) or caudate/putamen uptake, may further help with the image assessment.

The following precautions should be taken when using semi-quantitative methods:

- Semi-quantification should only be used as an adjunct to visual assessment
- Only CE marked software should be used
- Users should be trained in the use of CE marked software by the manufacturer and follow EANM practice guidelines for image acquisition, reconstruction and assessment
- Readers should interpret the scan visually and then perform the semi-quantitative analysis according to manufacturer's instructions including quality checks for the quantitation process
  - ROI /VOI techniques should be used to compare uptake in the striatum with uptake in a reference region
  - Comparison against an age adjusted healthy subjects database is recommended to account for age-expected decrease in striatal binding
  - The reconstruction and filter settings (including attenuation correction) used can affect the semi-quantitative values. The reconstruction and filter settings recommended by the manufacturer of the CE marked software should be followed and should match those used for semi-quantification of the healthy subjects database.
  - The intensity of the striatal signal as measured by SBR (striatal binding ratio) and asymmetry and caudate to putamen ratio provide objective numerical values corresponding to the visual assessment parameters and can be helpful in difficult to read cases
  - If the semi-quantitative values are inconsistent with the visual interpretation, the scan should be evaluated for appropriate placement of the ROIs /VOIs, correct image orientation and appropriate parameters for image acquisition and attenuation correction should be verified. Some software packages can support these processes to reduce operator-dependent variability
  - Final assessment should always consider both visual appearance and semi-quantitative results

#### 4.8 Undesirable effects

The following undesirable effects are recognised for DaTSCAN:

##### Summary of the safety profile

No serious adverse reactions related to DaTSCAN administration have been reported.

(...)

##### ***Skin and subcutaneous tissue disorders***

Not known: Erythema, pruritus, rash, urticaria, hyperhidrosis

##### ***Respiratory, thoracic and mediastinal disorders***

Not known: Dyspnea

##### ***Gastrointestinal disorders***

Uncommon: Nausea, dry mouth

Not known: Vomiting

### **Vascular disorders**

Not known: Blood pressure decreased

### **General disorders and administration site conditions**

Uncommon: Injection site pain (intense pain or burning sensation following administration into small veins)

Not known: Feeling hot

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is ~~4.35~~ 4.63 mSv when the maximal recommended activity of 185 MBq is administered these adverse events are expected to occur with a low probability.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/> and emailed to the Registration Holder's Patient Safety Unit at: [drugsafety@neopharmgroup.com](mailto:drugsafety@neopharmgroup.com)

### **6.3 Shelf-life**

The expiry date of the product is indicated on the packaging materials ~~2.5 ml vial: 7 hours from the activity reference time stated on the label~~

5 ml vial: 20 hours from the activity reference time stated on the label

## 9. DOSIMETRY

Target Organ	Absorbed radiation dose $\mu\text{Gy}/\text{MBq}$
Adrenals	13.117.0
Bone surface	15.0
Brain	18.116.0
Breasts	8.07.3
Gallbladder wall	25.744.0
Gastrointestinal tract	
- Stomach wall	12.0
- Small intestine wall	26.0
- Colon wall	59.0
- (Upper large intestine wall)	57.0
- (Lower large intestine wall)	42.462.0
- Small intestine	20.6
Stomach	11.4
Upper large intestine wall	38.132.0
Heart wall	13.1
Kidneys	11.113.0
Liver	28.385.0
Lungs	42.50
Muscles	9.68.9
Oesophagus	9.4
Ovaries	1718.0
Pancreas	13.217.0
Bone Red marrow	9.83
Salivary glands Bone surfaces	41.017.4
Skin	6.35.2
Spleen	10.626.0
Testes	8.86.3
Thymus	10.39.4
Thyroid	9.26.7
Urinary bladder wall	53.535.0
Uterus	16.314.0
Total body Remaining organs	11.510.0
<b>Effective Dose (<math>\mu\text{Sv}/\text{MBq}</math>)</b>	<b>25.0 <math>\mu\text{Sv}/\text{MBq}</math></b>

Ref.: Publication 128 of the Annals of ICRP (Radiation dose to Patients from Radiopharmaceuticals: A Compendium of Current Information Related to Frequently Used Substances)

The effective dose (E) resulting from administration of a 185 MBq dose of DaTSCAN injection is 4.35 4.63 mSv (per 70 kg individual). The above data are valid in normal pharmacokinetic behaviour. When renal or hepatic function is impaired, the effective dose and the radiation dose delivered to organs might be increased.

- העלון לרופא נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות.
- ניתן לקבל עלון זה מודפס על ידי פניה ישירה לבעל הרישום:  
אלדן ציוד אלקטרוני בע"מ, רח' השילוח 6, ת.ד. 7641, פתח תקווה 4917001, טלפון: 03-9371111.

בברכה, עוז וולך,  
רוקח ממונה עבור בעל הרישום אלדן ציוד אלקטרוני בע"מ

