Advanced Accelerator Applications

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BIR The British Institute of Radiology

ADVANCED ACCELERATOR APPLICATIONS WEBINAR AT BRITISH INSTITUTE OF RADIOLOGY (BIR)

You are cordially invited to attend a virtual meeting

DOPAVIEW (fluorodopa (18F)) for PET imaging in oncology and neurology

PROGRAMME

DATE:	**Wednesday, 25th November 2020**	
TIME:	**19:00–20:30**	
	Chairs: ***Professor Jamshed Bomanji*** *Clinical Lead and Head of Department at the Institute of Nuclear Medicine, University College London Hospitals NHS Foundation Trust, UK* ***Dr Nicola Mulholland*** *Consultant Radiologist and Nuclear Medicine Physician, King's College Hospital, London UK*	
19:00–19:10	**Introduction**	
19:10–19:35	**^{18}F-DOPA PET in endocrine malignancies**	***Professor David Taïeb*** *Professor in Nuclear Medicine La Timone University Hospital, Marseille, France*
19:35–20:05	**DOPAVIEW in neurology**	***Professor Jacques Darcourt*** *Professor of Biophysics and Nuclear Medicine Centre Antoine Lacassagne, Nice, France*
20:05–20:30	**Panel discussion**	
20:30	**Close**	

This webinar is for healthcare professionals only.

This meeting has been organised and funded by Advanced Accelerator Applications, a Novartis company.
Advanced Accelerator Applications products will be discussed at this meeting.

Prescribing information can be found overleaf.

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PRESCRIBING INFORMATION

DOPAVIEW 222 MBq/mL solution for injection.

Prescribing Information

DOPAVIEW 222 MBq/mL solution for injection. One mL contains 222 MBq of fluorodopa (18F) or 6-fluoro-(18F)-Ldihydroxyphenylalanine (or 6-fluoro-(18F)-L-dopa) at date and time of calibration. **Presentation:** Solution for injection. Clear and colourless or slightly yellow solution. Osmolality: 300 mOsm/kg (approx.). pH: 4.0 – 4.5. **Uses:** DOPAVIEW is indicated for use with positron emission tomography (PET) in adults and paediatric population; for diagnostic use only within the neurology and oncology sectors. **Administration:** *Paediatric population* – The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activity to administer to children or adolescents can be calculated as follows, according to the recommendations of the European Association of Nuclear Medicine (EANM) task force: 1) PET 3D acquisition mode is strongly recommended, using the following formula: activity administered [MBq] = 14 x multiplication factor (please consult DOPAVIEW SmPC), minimum activity = 14MBq. 2) If only PET 2D acquisition mode is available, use the following formula: activity administered [MBq] = 25.9 x multiplication factor (please consult DOPAVIEW SmPC), minimum activity = 26MBq. *Adults and elderly population* – In oncology, the activity generally recommended for adults is 2 to 4 MBq/kg of body mass (this activity has to be adapted according to the type of camera used PET(/CT), and acquisition mode), administered by direct slow intravenous injection over approximately one minute. In neurology, the activity generally recommended for adults is 1 to 2 MBq/kg of body mass (this activity has to be adapted according to the type of camera used PET(/CT) and acquisition mode), administered by direct slow intravenous injection over approximately one minute. *Renal / Hepatic impairment* – Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients. **Method of administration:** The activity of DOPAVIEW has to be measured with an activimeter immediately prior to injection. The product must be administered only by intravenous injection in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts. *Patient preparation* – The patient should be fasting for a minimum of 4 hours without limiting water intake (glucose solution administration is permitted for procedures performed to investigate hyperinsulinism). The injection must be slow and administered via the intravenous route only. In order to obtain images of best quality and to reduce the radiation exposure of the bladder, patients should be encouraged to drink sufficient amounts and to empty their bladder prior to and after the PET examination. In neurological indications, it is recommended to suspend any antiparkinsonian treatment at least 12 hours before the PET examination. **Contraindications:** Hypersensitivity to the active substance, to any of the excipients listed in section 6.1 of the DOPAVIEW SmPC. Pregnancy. **Special warnings and precautions for use:** *Potential for hypersensitivity or anaphylactic reactions* – If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available. *Individual benefit / risk justification* – For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information. *Renal / hepatic impairment* – Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible. *Paediatric population* – For information on the use in paediatric population, see above. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults. *Interpretation of DOPAVIEW PET images – Neurology* – The interpretation of fluorodopa (18F) uptake values in the different parts of the brain requires the comparison to age and sex matched controls. Recent publications refer to data base of normal cases and voxel-based Statistical Parametric Mapping (SPM) and automated region of interest (ROI) analysis. *Oncology* – False positive results in inflammatory lesions seem to be very rare with fluorodopa (18F) PET. Nevertheless, the possibility of an inflammatory lesion should be kept in mind when an unexpected fluorodopa (18F) focus is detected. The physiologic biodistribution must be taken into account in the interpretation; in particular uptake in the basal ganglia, diffuse uptake in the pancreas, uptake in the gallbladder leading to subsequent activity in the gut, and uptake in the kidney leading to “hot spots” aspect in the ureters and a high activity in the bladder. *After the procedure* – Close contact with infants and pregnant women should be restricted during the initial 12 hours following the injection. *Specific warnings* – Depending on the time when you administer the injection prepared extemporaneously after pH adjustment, the content of sodium given to the patient may in some cases be greater than 1 mmol (23 mg). This should be taken into account in patient on low sodium diet. *Precautions with respect to environmental hazard* – See section 6.6 of DOPAVIEW SmPC. **Undesirable effects:** Pain at injection has been reported in rare cases (probably due to the acidity of the radiopharmaceutical formulation [pH 4-4.5]) that disappeared within a few minutes without treatment. Exposure to ionising radiation may affect fertility, induce cancer or cause a number of functional disorders such as blood or renal function disorders. Experience has shown that the frequency of these undesirable effects for nuclear medicine imaging is very rare, given the low activities used. The effective dose is 7 mSv of DOPAVIEW when the maximal recommended activity is administered to an adult weighing 70 kg. *Paediatric population* – Not reported. **Marketing Authorisation Holder:** Advanced Accelerator Applications 20 rue Diesel 01630 Saint Genis Pouilly France **Marketing Authorisation Number:** PL 35145/0001 **Legal Category:** POM **Price:** £3020 per 350MBq vial **Date of preparation of PI:** September 2020

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Advanced Accelerator Applications at: uk.patientsafety@novartis.com

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