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Summary of the Risk Management Plan (RMP) for Neuraceq® (florbetaben (18F)

Neuraceq 300 MBq/ml Solution for Injection

EU Risk Management Plan Version 6.0, dated 16-Feb-2021

Document dated 24-June-2021

Disclaimer:
The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Neuraceq 300 MBq/ml Solution for Injection is a concise document and does not claim to be exhaustive.
As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Neuraceq 300 MBq/ml Solution for Injection in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.
SWAN Isotopen AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Neuraceq 300 MBq/ml Solution for Injection.

Part VI: Summary of the risk management plan

Summary of risk management plan for Neuraceq (florbetaben (^{18}F)

This is a summary of the risk management plan (RMP) for Neuraceq. The RMP details important risks of Neuraceq, how these risks can be minimised, and how more information will be obtained about Neuraceq's risks and uncertainties (missing information).

Neuraceq's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Neuraceq should be used.

This summary of the RMP for Neuraceq should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Neuraceq's RMP.

I. The medicine and what it is used for

Neuraceq is authorised for Positron Emission Tomography (PET) imaging of β-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. Neuraceq should be used in conjunction with a clinical evaluation. (see SmPC for the full indication). It contains florbetaben (^{18}F) as the active substance and it is given by intravenous injection.

Further information about the evaluation of Neuraceq's benefits can be found in Neuraceq's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002553/human_med_001716.jsp&mid=WC0b01ac058001d124.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Neuraceq, together with measures to minimise such risks and the proposed studies for learning more about Neuraceq's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Neuraceq, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Neuraceq is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Neuraceq are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Neuraceq. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	PET scan interpretation errors
Missing information	None

II.B Summary of important risks

Important potential risk: PET scan interpretation errors	
Evidence for linking the risk to the medicine	Study 14595-Report A0002 and Study FBB_01_01_13-Report A0001
Risk factors and risk groups	Patients with brain abnormalities; motion artefacts.
Risk minimisation measures	Routine risk minimization measures: • SmPC sections 4.1, 4.2, 4.4 and 5.1 • Legal status: Medicinal product subject to restricted medical prescription. • A PET scan with florbetaben (^{18}F) should be requested by clinicians experienced in the clinical management of neurodegenerative disorders. Neuraceq images should only be interpreted by readers trained in the interpretation of PET images with florbetaben (^{18}F). Additional risk minimization measures: • Training of PET scan readers with educational material
Additional pharmacovigilance activities	None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Neuraceq.

II.C.2 Other studies in post-authorisation development plan

Not applicable.