VIZAMYL 150MBq/ml, solution for injection (flutemetamolum ^{18}F)

Summary of Risk Management Plan

Version 6 (based on RMP v4.0)

Date of report: December 2022

Marketing Authorisation Holder:

GE Healthcare AG, 8152 Opfikon, Switzerland

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 minimize them.

The RMP summary of Vizamyl 150MBq/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 Vizamyl 150MBq/ml, solution for injection in Switzerland is the "Arzneimittelinformation/Information sur le médicament" (see www. Swissmedic.ch) approved and authorized by Swissmedic. GE Healthcare AG is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Vizamyl 150MBq/ml, solution for injection .

Summary of the risk management plan (RMP) for Vizamyl (flutemetamolum ^{18}F)

This summary of the RMP for Vizamyl solution for injection 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 Vizamyl's RMP.

I. The medicine and what it is used for

Vizamyl 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 (see the "Arzneimittelinformation/Information sur le médicament" for the full indication approved by Swissmedic and in addition by EMA. It contains flutemetamol (^{18}F) as the active substance and it is given by intravenous route of administration.

Further information about the evaluation of Vizamyl's benefits can be found in Vizamyl's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/Vizamyl.

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

Important risks of Vizamyl, together with measures to minimise such risks and the proposed studies for learning more about Vizamyl'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 Vizamyl, 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.

II.A List of important risks and missing information

Important risks of Vizamyl 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 Vizamyl. 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 imaging interpretation errors
Missing information	None

II.B Summary of important risks

Important potential risk PET imaging interpretation errors	
Evidence for linking the risk to the medicine	The evidence was obtained from clinical studies and from post-authorisation study GE067-027, together with a root-cause analysis of the factors predictive of clinical reader's diagnostic accuracy in interpreting Vizamyl images.
Risk factors and risk groups	PET image readers that are either not sufficiently trained or do not follow the instructions provided in the training are a risk factor as they are more likely to produce inaccurate image interpretations. Especially in patients with considerable brain atrophy there is a risk of image interpretation errors. Failure to follow the recommended method for image interpretation has been shown to increase the chances of image misinterpretation.
Risk minimisation measures	<u>Routine risk minimisation measures:</u> – SmPC sections 4.2 and 4.4 (resp. dosage/administration and warnings/precautions), – Vizamyl is available by prescription only. <u>Additional risk minimisation measure:</u> – Educational programme consisting of initial reader training, refresher training, and optional training on quantitative analysis of Vizamyl PET images.
Additional pharmacovigilance activities	<u>Additional pharmacovigilance activities:</u> – Web-based questionnaire See section II.C of this summary for an overview of the post-authorisation development plan.

II.C Post-authorisation development plan

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

There are no studies that are conditions of the marketing authorisation or specific obligation of Vizamyl.

II.C.1 Other studies in post-authorisation development plan

Study short name: Web-based questionnaire

Purpose of the study: Compliance with the recommended image read methods will be assessed by a web-based questionnaire that will check the readers understanding of the steps of the Vizamyl image interpretation methodology.