

# Summary of risk management plan for Fludeomap (fludeoxyglucose ( $^{18}\text{F}$ ))

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

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

## **I. The medicine and what it is used for**

Fludeomap is authorised for use in positron emission tomography (PET imaging) in adults and children (see SmPC for the full indication). It contains fludeoxyglucose ( $^{18}\text{F}$ ) as the active substance and it is given by intra-venous injection.

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

Important risks of Fludeomap, together with measures to minimise such risks and the proposed studies for learning more about Fludeomap'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, such as warnings, precautions, and advice on correct use;
- 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 public (e.g. with or without prescription) can help to minimise its risks.

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

In addition to these measures, information about adverse events is collected continuously and regularly analysed 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 Fludeomap 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 Fludeomap. 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);

<b>List of important risks and missing information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

## ***II.B Summary of important risks***

The safety information in the proposed Product Information is aligned to the reference medicinal product.

## ***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 Fludeomap.

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

There are no studies required for Fludeomap.