

**ANNEX**

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE  
OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

## **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

The Member States shall ensure that the following conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The MAH shall ensure that all Healthcare Professional who are expected to prescribe/use Fabrazyme are provided with an educational pack aiming to facilitate the training of the patients/caregivers and also to guide prescribers regarding patient evaluation and selection and organisational requirements for home infusion.

The educational pack should contain the following:

- Home infusion manual for healthcare professionals
- Home infusion manuals for patients
- Summary of Product Characteristics and Package Leaflet

The educational material for healthcare professionals should include information on the following key elements:

- Guidance regarding patient evaluation and selection and organisational requirements for home infusion.
- That it is the responsibility of the prescribing physician to determine which patients may be suitable for home or self-administration of Fabrazyme.
- That it is the responsibility of the prescribing physician to provide appropriate training to the non-healthcare professional, such as the patient for self-administration or a caregiver who will administer the treatment at home, if the treating physician decides that this is appropriate.
- Regular review of the administration by the patient and/or caregiver needs to be performed to ensure maintenance of optimal practice.
- The training to be provided to the patient and /or caregiver should address the following elements:
  - That it is essential to follow strictly the prescribed dose and infusion rate
  - Method of preparation and administration of Fabrazyme
  - Instructions in handling possible adverse events
  - Instruction to seek emergency treatment by healthcare professionals in the event of any adverse reactions during an infusion
  - The need to seek urgent treatment in the event of failure to gain venous access or if there is a lack of efficacy
  - The need to keep a diary to document each treatment received at home and to bring it at each visit
- It is the responsibility of the prescribing physician to verify that all necessary skills have been acquired by the non-healthcare professional and that Fabrazyme may be safely and effectively administered at home.

The educational material for patients should include information on the following key elements:

- The prescribing physician may decide that Fabrazyme may be administered at home. The level of support required for home infusion will be discussed and agreed by the patient and/or caregiver with the prescribing physician.
- The treating physician will be responsible for determining which patients may be suitable for home or self-administration of Fabrazyme and for arranging for treatment at home and training the patient and/or caregiver in the appropriate skills necessary for this.
- Necessary skills have to be acquired by non-healthcare professionals before Fabrazyme may be safely and effectively administered at home.

- Their prescribing physician will provide training on the following elements:
  - That it is essential to follow strictly the prescribed dose and infusion rate
  - Method of preparation and administration of Fabrazyme
  - Instructions in handling possible adverse events
  - Instruction to seek emergency treatment by healthcare professionals in the event of any adverse reactions during an infusion
  - The need to seek urgent treatment in the event of failure to gain venous access or if there is a lack of efficacy
  - The need to keep a diary to document each treatment received at home and to bring it at each visit