

ANNEX

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

The Member States must ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented in their national territory:

- Prior to launch of the product in the Member State, the national competent authority shall agree the content and format of the educational material with the Marketing Authorisation Holder
- The Marketing Authorisation Holder (MAH) should ensure that, at launch, all Healthcare Professionals who are expected to prescribe Cinryze are provided with an Educational pack.

The educational pack should contain the following:

- Summary of Product Characteristics and Patient Information Leaflet for Cinryze
- Educational material for Healthcare Professionals
- Educational materials for non Healthcare Professionals

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

There are limited data on the use of this medicinal product in home or self-administration.

It is the responsibility of the prescribing physician to determine which patients may be suitable for home or self-administration of Cinryze

It is the responsibility of the prescribing physician to provide appropriate training to the non-healthcare professional who will administer the treatment at home, such as the patient for self-administration or a family member. Regular review of the administration by the patient/carer needs to be performed to ensure maintenance of optimal practice.

The training to be provided should address the following elements

Precaution for storage

Doses and Indications of treatment

Preparation of one dose of Cinryze (1000 Units) by reconstituting two vials

Method of reconstitution of each vial

Technique of intravenous injection

Method and rate of administration of one dose of Cinryze (1000 Units)

Instruction to seek emergency treatment by health care professionals in case of failure to gain venous access or in case of lack of efficacy

Instruction in handling possible adverse drug reactions

Information on the need to keep a diary to document each treatment received at home and to bring it at each visit. The information collected should include:

Date and time of treatment

Batch number and dose received

Indication for treatment (acute attack or prophylaxis)

Response to treatment

Any adverse reactions

It is the responsibility of the prescribing physician to verify that all the necessary skills have been acquired by the non-healthcare professional and that Cinryze may be safely and effectively administered at home.

The existence of a post marketing registry in which health care professionals are encouraged to enter patients

The educational material for non Healthcare Professionals should include information on the following key elements:

There are limited data on the use of this medicinal product in home or self-administration.

For some patients the prescribing physician may decide that Cinryze may be administered at home by a non Healthcare Professional such as a family member or by self-administration.

Necessary skills have to be acquired by non-healthcare professionals before Cinryze may be safely and effectively administered at home.

Their prescribing physician will provide training on the following elements:

Precaution for storage

Doses and Indications of treatment

Preparation of one dose of Cinryze (1000 Units) by reconstituting two vials

Method of reconstitution of each vial

Technique of intravenous injection

Method and rate of administration of one dose of Cinryze (1000 Units)

Instruction to seek emergency treatment by health care professionals in case of failure to gain venous access or in case of lack of efficacy

Instruction in handling possible adverse drug reactions

Information on the need to keep a diary to document each treatment received at home and to bring it at each visit. The information collected should include:

Date and time of treatment

Batch number and dose received

Indication for treatment (acute attack or prophylaxis)

Response to treatment

Any adverse reactions

A leaflet providing detailed information on the key elements of the training that should be kept at home for further reference.