

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 should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

Prior to launch in each member State the MAH shall agree the final educational material with the National Competent Authority.

The MAH shall ensure that, at launch, all physicians, pharmacists and patients expected to prescribe/use PecFent are provided with educational material informing about the correct and safe use of the product.

Educational material for patients should highlight the following:

- Instructions for use of the nasal spray device
- Instructions for opening and closing of the child-resistant box
- Information on the correct indication
- Only use PecFent nasal spray if you are using other opioid pain medicine on a daily basis
- Only use PecFent nasal spray if you have been experiencing breakthrough cancer pain episodes
- Do not use PecFent nasal spray to treat any other short-term pain or pain status
- Do not use PecFent nasal spray for treatment of more than four breakthrough cancer pain episodes a day
- Only use PecFent nasal spray if you have received the proper information regarding the use of the device and the safety precautions from the prescriber and/or the pharmacist
- All unused devices or empty containers should be returned systematically according to the local regulation

Educational material for physicians should highlight the following:

- PecFent nasal spray should be prescribed only by physicians experienced in the management of opioid therapy in cancer patients.
- The prescribers of PecFent nasal spray must critically select the patients and closely follow
 - Instructions for use of the nasal spray device
 - Instructions for opening and closing of the child-resistant box
 - Information on the correct indication
- PecFent nasal spray should not be used to treat any other short-term pain or pain status.
- All unused devices or empty containers should be returned systematically according to the local regulation.
- The prescriber must make use of the checklist for prescribers

Educational material for pharmacists should highlight the following:

- PecFent nasal spray is only indicated for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain
- PecFent nasal spray should not be used to treat any other short-term pain or pain status
- The pharmacist must be familiar with the educational material of PecFent nasal spray before using it in his/her organization
- The PecFent nasal spray dose strengths can not be compared with other PecFent products
- Instructions for use of the nasal spray device
- Instructions for opening and closing of the child-resistant box
- The pharmacist must inform the patients that in order to prevent theft and misuse of PecFent nasal spray they have to keep it in a safe place to avoid misuse and diversion
- All unused devices or empty containers should be returned systematically according to the local regulation
- The pharmacist must make use of the checklist for pharmacist