Summarized Information\_English

Informations résumées\_Français

Samengevatte informatie\_Nederlands

# Summarized Information\_English

|  |  |
| --- | --- |
| Product Name |  |
| Active substance |  |
| Indication and conditions of use | Provide a short description to describe the indication intended to treat and the conditions of use (posology, administration precautions, …) |
| Conditions, delays and further rules for participation of patients | Clearly describe the inclusion and exclusion criteria for the patients, specific timelines on the treatment of the request by the treating physician and other information that might be relevant for a patient |
| Duration of the program | When will this program start ? Is the inclusion of patients dependent on a cohort decision or are patients accepted as soon as the program is authorized ?When will the program end ? |
| Conditions of distribution | How will patients have access to the medicinal product ? Timelines? |
| Responsible of the program | Please provide contact data (Name, address, phone number, email). In case of a separate contact person for questions, this can be mentioned here as well.  |
| Modalities for the disposal | How should unused or expired medicinal product be disposed off. |
| The information for registration of suspected unexpected serious adverse reactions | Provide a list of expected serious adverse reactions (Reference Safety Information or RSI) as illustrated below:

|  |  |  |
| --- | --- | --- |
| System Organ Class(MedDRA) | SARs | Number of subjects exposed (N) = … |
| All SARs | Occurrence of fatal SARs | Occurrence of life threatening SARs |
| n\* (%)  | n (%)  | n (%) |
|  |  |  |  |  |

As with clinical trials, previously observed events should be relied upon rather than what might be expected from the pharmacological properties of a medicinal product. In this way it can be determined whether or not a serious adverse reaction should be classified as a suspected unexpected serious adverse reaction (SUSAR). |

# Informations résumées\_Français

|  |  |
| --- | --- |
| Nom du médicament |  |
| Nom de la substance active |  |

|  |  |
| --- | --- |
| Indication et conditions d’utilisation  |  |
| Conditions, délais et modalités selon lesquels les patients sont admis dans le programme |  |
| Durée |  |
| Conditions de distribution |  |
| Responsable  |  |
| Modalités selon lesquelles les médicaments non-utilisés sont traités |  |
| Données pour l’enregistrement des suspicions d’effetsindésirables inattendus graves |  |

# Samengevatte informatie\_Nederlands

|  |  |
| --- | --- |
| Naam geneesmiddel |  |
| Naam actieve substantie |  |

|  |  |
| --- | --- |
| Indicatie en gebruiksvoorwaarden  |  |
| Voorwaarden, termijnen en nadere regelen waaronder patiëntenworden toegelaten  |  |
| Looptijd |  |
| Distributievoorwaarden |  |
| Verantwoordelijke  |  |
| Modaliteiten voor de behandeling van niet-gebruikt geneesmiddel |  |
| Gegevens voor de registratie van vermoedens van onverwachte ernstige bijwerkingen |  |