Summarized Information for publication\_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  |
| 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 adverse reactions. As for clinical trials, this should be done from the perspective of events previously observed, not on the basis of what might be anticipated from the pharmacological properties of a medicinal product. |

# 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 graves |  |

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# 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 bijwerkingen |  |