**Declaration for the amendment of information on patented indications/doses in the summary of product characteristics (SmPC) and package leaflet**

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| --- | --- |
| Name of the medicine: |  |
| Active ingredient: |  |
| Authorisation number: |  |
| Date of last approved SmPC: |  |
| Date of last approved package leaflet: |  |
| Patented indication: |  |
| Product counter: |  |

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| --- | --- |
|  | Only the information on the patented indication in sections 4.1, 4.2 and 5.1 of the SmPC and the corresponding sections of the package leaflet has been removed. |
|  | The safety information in sections 4.3 to 4.9 of the SmPC and the corresponding sections of the package leaflet relating to the patented indication will remain. |
|  | The package leaflet contains the following standard sentence: "<Product name> contains the active substance <substance name>, which is also used in the treatment of conditions not listed in this package leaflet. Please contact your doctor or pharmacist if you have any questions." |
|  | However, if information in sections 4.3 to 4.9 of the SmPC has been removed or changed, for example removal of text traceable to the patented indication, this has been justified. |
|  | After the patent expired, the information on the previously patented indication was included in the SmPC and package leaflet. |

I, the undersigned, declare that this form has been completed truthfully.

|  |  |
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| Marketing authorisation holder: |  |
| Contact name: |  |
| Email address: |  |
| Job title: |  |
| Date: |  |
| Signature: |  |