# RISK MANAGEMENT PLAN

|  |  |
| --- | --- |
| **Active substance(s) (INN or common name):** |  |
| **Pharmaco-therapeutic group (ATC Code):** |  |
| **Name of Marketing Authorization Holder or Applicant:** |  |
| **Number of medicinal products to which this RMP refers:** |  |
| **Product(s) concerned (brand name(s)):** |  |

Data lock point for this RMP:

Version number:

Date off siginal off:

# Table of contents:

# List of abbreviations:

# List of tables:

# 

# Part I: Product(S) overview:

Administrative information on theRMP

|  |  |  |  |
| --- | --- | --- | --- |
| **Part** | **Module/annex** | **Date last Updated for submission (sign off date)** | **\*Version numberof RMP when last submitted** |
| **PartII** SafetySpecification | SV Post authorization experience |  |  |
|  | SVIII Summaryof thesafetyconcerns |  |  |
| **PartIII** Pharmacovigilance Plan |  |  |  |
| **PartIV** Planfor post-authorization efficacystudies | Onlyneededifreferenceproducthas imposed post-authorizationefficacystudies |  |  |
| **PartV** RiskMinimization Measures |  |  |  |
| **PartVI** Summaryof RMP |  |  |  |
| **Part VII** Annexes | ANNEX 2 Currentor proposed SmPC/PIL |  |  |
|  | ANNEX 3 Worldwide marketingstatus bycountry |  |  |
|  | ANNEX 5 Synopsis of pharmacoepidemiological study program |  |  |
|  | ANNEX 6 Protocols forproposedandon-goingstudies in PartIII |  |  |
|  | ANNEX 7 Specific adverse eventfollow-up forms |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Part** | **Module/annex** | **Date lastupdated for submission (sign off date)** | **\*Version numberof RMPwhen last submitted** |
|  | ANNEX 8 Protocols for studiesin PartIV |  |  |
|  | ANNEX 9 Synopsisofnewlyavailablestudyreportsin Parts III-IV |  |  |
|  | ANNEX 10 Detailsof proposed additionalrisk Minimizationactivities |  |  |
|  | ANNEX 11 Mockup examples |  |  |
|  | ANNEX 12 Othersupportingdata |  |  |

**Table 1: Administrative information on the RMP**

**QPPV name:**

**Contact person for this RMP:**

**E-mail address**:

**Telephone number**

**Signature:**

# Overview of versions:

***Version numberof last agreed RMP:***

* Version number
* Agreedwithin

**Current RMP versions under evaluation:**

|  |  |  |
| --- | --- | --- |
| **RMP Version number** | **Submitted on** | **Submitted within** |
|  |  |  |

|  |  |
| --- | --- |
| **Invented name(s) in the Arab country concerned** |  |
| **Brief description of the product including:**  **Chemical class**  **Summary of mode of action**  **Important information aboutits composition** | **Chemical class:**  **Summary of mode of action:**  **Important information about its composition:** |
| **Indication(s)** | **Current(if applicable) inthe Arab Country concerned** |
| **Currentof the reference medicinal product.** |
| **Proposed in the Arab Country concerned** |
| **Thatof the reference product:** |
| **Posology and routeof administration in the Arab Country concerned** | **Current(if applicable) inthe Arab Country concerned** |
| **Currentof the reference medicinalproduct:** |
| **Proposed (ifapplicable)inthe Arab Countryconcerned** |
| **That of the reference product:** |
| **Pharmaceuticalform(s) and strengths** | **Current (if applicable) in the Arab Country concerne** |
| **Current of the reference medicinal product** |
| **Proposed (ifapplicable)inthe Arab Countryconcerned** |
| **Thatof the reference product** |

**Table 2: General overview for each product in the RMP**

Countryand date of first authorization worldwide

Countryand date of first launch worldwide

Dateof first authorization (ifauthorized) inthe   
Arab Countryconcerned

Is the product subject toadditional monitoring? Yes🞎 No 🞎

**Name of reference product**:

**MAH**:

# Part II: Module SV - Post-authorization experience:

## *SV.1.Action taken by regulatory authorities and/or marketing authorization holders for safety reasons*

## *SV.2.Non-study post-authorizationexposure*

### SV.2.1.Method used to calculate exposure

### SV.2.2. Exposure

## *SV.3.Post-authorization use in populations not studied in clinical trials*

## *SV.4.Post-authorization off-label use*

## *SV.5. Epidemiological study exposure*

# Part II:Module SVIII - Summary of the safety concerns:

**Summary of safety concerns**

|  |  |
| --- | --- |
| **Summary of safety concerns**  **Summary ofsafety concerns** | |
| **Important identified risks** |  |
| **Important potential risks** |  |
| **Missinginformation** |  |

**Table 3:** **Summary of Safety concerns**

# PartIII: Pharmacovigilance Plan

## *III.1 Safety concerns and overview of planned pharmacovigilance actions*

|  |  |  |
| --- | --- | --- |
| **Safety concern 1** | | |
| **Areas requiring confirmation or further investigation** | **Proposed routine and additional Pvactivities** | **Objectives** |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **Safety concern 2** | | |
| **Areas requiring confirmation or further investigation** | **Proposed routine and additional Pvactivities** | **Objectives** |
|  |  |  |

## *III.2. Additional pharmacovigilance activities to assess effectiveness of risk Minimization measures*

## *III.3. Studies and other activities completed since last update of Pharmacovigilance Plan*

## *III.4. Details of outstanding additional pharmacovigilance activities*

## *III.5. Summary of pharmacovigilance plan*

# Part IV: Plans for post-authorization efficacy studies

## *IV.1. Applicability of efficacy to all patients in the target population*

## *IV.2. Tables of post-authorization efficacy studies*

## *IV.3. Summary of post authorization efficacy development plan*

## *IV.4. Summary of completed post authorization efficacy studies*

# Part V: Risk minimization measures

## *V.1 Risk Minimization measures by safety concern:*

|  |  |
| --- | --- |
| **1-Safety concern** |  |
| **Objective(s) of the risk Minimization measures** |  |
| **Routine risk Minimization measures** | **(Proposed) text in SmPC** |
|  | Comment: |
| Other routine risk minimization measures : |
| **Additional risk minimization measure(s)** |  |

|  |  |
| --- | --- |
| **Effectiveness of risk minimization measures** | |
| How effectiveness of risk minimization measures for the safety concern will be measured |  |
| Criteria for judging the success of the proposed risk minimization measures |  |
| Planned dates for assessment |  |
| Results of effectiveness measurement |  |
| Impact of risk minimization measure |  |
| Comment |  |

## 

## *V.2. Risk Minimization measure failure (if applicable)*

### V.2.1. Analysis of risk Minimization measure(s) failure

### V.2.2. Revised proposal for risk Minimization

## *V.3. Summary table of risk Minimization measures*

|  |  |  |
| --- | --- | --- |
| **Safety concern** | **Routine risk minimization measures** | **Additional risk minimization measures** |
|  | **(Proposed) text in SmPC** |  |

# Part VI: Summary of the risk management plan by product

## *VI.I summary of safety concerns:*

|  |  |
| --- | --- |
| **Summary of safety concerns**  **Summary ofsafety concerns** | |
| **Important identified risks** |  |
| **Important potential risks** |  |
| **Missinginformation** |  |

**Important identified risks**

|  |  |  |
| --- | --- | --- |
| **Risk** | **What is known** | **Preventability** |
| Safety concern 1 |  | **(Proposed) text in SmPC** |

**Important potential risks**

|  |  |
| --- | --- |
| **Risk** | **Whatis known** |
| **Safety concern 1** |  |

**Missing information**

|  |  |
| --- | --- |
| **Risk** | **What is known** |
|  |  |

## *VI.2. Summary of Risk Minimization measures by safety concern*

|  |  |  |
| --- | --- | --- |
| **Safety concern** | **Routine risk minimization measures** | **Additional risk minimization measures** |
| Safety concern 1 |  |  |

## *VI.3. Planned Post authorization development plan*

### List of studies in post authorization development plan:

### Studies which are a condition of the marketing authorization:

## *VI.4. Summary of changes to the Risk Management Plan over time:*

# Part VII: RMP Annexes

* **Annex 1**-National Pharmacovigilance and Safety reports database‖/"National Pharmacovigilance Issues Tracking Tool" Interface
* **Annex 2** - SmPC & Package Leaflet
* **Annex 3** - Worldwide marketing authorization by country (including Arab Country(s) concerned)
* **Annex 4** - Synopsis of on-going and completed clinical trial programme
* **Annex 5 -** Synopsis of on-going and completed pharmacoepidemiological study programme
* **Annex 6** - Protocols for proposed and on-going studies in the section ―Summary table of additional pharmacovigilance activities‖ in RMP Part III
* **Annex 7** - Specific adverse event follow-up forms
* **Annex 8** - Protocols for proposed and on-going studies in RMP Part IV
* **Annex 9** - Newly available study reports for RMP Parts III & IV
* **Annex 10** - Details of proposed additional risk Minimization measures (if applicable)
* **Annex 11 -** Mock-up of proposed additional risk Minimization measures (if applicable)
* **Annex 12** - Other supporting data (including referenced material)

## *RMP Annex 1 - National Pharmacovigilance and Safety reports database/"National Pharmacovigilance Issues Tracking Tool" Interface*

## *RMP Annex 2 - SmPC & Package Leaflet*

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## *RMP Annex 3 - Worldwide marketing authorization by country (including Arab Country(s) concerned):*

### A3.1 licensing status in the Arab Country(s) concern:

### A3.2.Licensing status in the rest of the world:

*RMP Annex 4 - Synopsis of on-going and completed clinical trial program:*

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## *RMP Annex 5 - Synopsis of on-going and completed pharmacoepidemiological study program:*

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## *RMP Annex 6 - Protocols for proposed and on-going studies in the section “Summary table of additional pharmacovigilance activities” in RMP part III*

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## *RMP Annex 7 - Specific adverse event follow-up forms*

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## *RMP Annex 8 - Protocols for proposed and on-going studies in RMP part IV:*

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## *RMP Annex 9 - Newly available study reports for RMP parts III & IV*

## *RMP Annex 10 - Details of proposed additional risk minimisation measures (if applicable)*

## 

## *RMP Annex 11 - Mock-up of proposed additional risk minimization measures (if applicable)*

## *RMP Annex 12 - Other supporting data (including referenced material*