# Periodic benefit risk evaluation report (PBRER)

**Product name:**

**Active substance:**

**ATC code:**

* **Name of** **the medicinal** **Product**
* **Reporting interval** :
* **IBD of the product:**
* **MAH’s name:**

|  |  |
| --- | --- |
| **Name & contact details of the QPPV:** | |
| * **Name** |  |
| * **Office address** |  |
| * **Telephone number** |  |
| * **Fax number** |  |
| * **E-mail address** |  |
| * **Signature of the QPPV** |  |

**Statement of confidentiality:**

# Executive summary:

# List of abbreviations

# Section 1: Introduction

* **IBD:**
* **Reporting interval**
* **Therapeutic class:**
* **Mechanism of action:**
* **Authorized indications:**
* **Pharmaceutical form:**
* **Dose :**
* **Route of administration:**
* **Treated population:**

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# Section2. Worldwide marketing authorization status:

# Section3. Actions taken due to safety reasons:

## 3.1. Actions related to investigational uses:

## 3.2. Actions related to marketing experience:

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# Section 4.Changes to reference safety information:

# Section 5.Estimated exposure:

## 5.1 Cumulative subject exposure in clinical trials:

## 5.2 Cumulative and interval patient exposure from marketing experience

# 6. Data in summary tabulations:

## 6.1. Reference information:

## 6.2. Cumulative summary tabulations of serious adverse events from clinical trials:

## 6.3. Cumulative and interval summary tabulations from post marketing data sources:

# Section 7.Summaries of significant findings from clinical trials during the reporting interval:

## 7.1. Completed clinical trials:

Not applicable for the generic products

## 7.2. Ongoing clinical trials:

Not applicable for the generic products

## 7.3. Long term follow-up:

Not applicable for the generic products

## 7.4 Other therapeutic use of medicinal products:

Not applicable for the generic products

## 7.5 New safety data related to fixed combination therapies:

Not applicable for the generic products

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# Section8. Findings from non-interventional studies:

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# Section9. Information from other clinical trials and sources:

## 9.1. Other clinical trials:

Not applicable for the generic products.

## 9.2. Medication errors:

### *9.2.1. Medication error reports:*

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### *9.2.2. Other categories:*

### *9.2.3. Use in special populations:*

# Section10. Non-clinical data:

*Not applicable for the generic products.*

# Section11. Literature:

# Section12. Other periodic reports:

# Section13. Lack of efficacy in controlled clinical trials:

Not applicable for the generic products.

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# Section14. Late breaking information:

# Section15. Overview of signals: new, ongoing or closed:

# Section16. Signal and risk evaluation:

## 16.1. Summary of safety concerns:

## 16.2. Signal evaluation:

## 16.3. Evaluation of risks and new information:

## 16.4. Characterization of risks

## 16.5. Effectiveness of risk minimization (if applicable):

# Section17. Benefit evaluation

## 17.1. Important baseline efficacy and effectiveness information:

## 17.2. Newly identified information on efficacy and effectiveness:

## 17.3. Characterization of benefits:

# Section 18.integrated benefit-risk analysis for authorized indications:

## 18.1 Benefit-risk context-medical need and important alternatives:

## Benefit-risk analysis evaluation:

# Section 19.Conclusions and actions:

# Section20. Appendices to PSUR:

## 1-National appendix

### *1.1 SmPC- Summary of product characteristics*

### *1.2 Proposed product information:*

### *1.3 Proposed additional and pharmacovigilance activities:*

### *1.4 Summary of ongoing safety concerns:*

### *1.5 Worldwide marketing authorization status table:*