Medicines Control Authority of Zimbabwe

EVRF 82

ZIMBABWE PUBLIC ASSESSMENT REPORT (ZIMPAR) FOR REGISTERED MEDICINES

Roflumilast 250 mcg Tablets (Flairof)

Medicine Status: Registered

Name of FPP Manufacturer: Hetero Labs Limited

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1.0 Introduction

1. **Medicine Overview**: Roflumilast 250 mcg tablets, marketed as Flairof, is a generic medicine containing roflumilast as the main active ingredient.
2. **Mechanism of Action:** Roflumilast is a selective phosphodiesterase-4 (PDE4) inhibitor. Its molecular mechanism of action involves inhibiting the PDE4 isoenzyme, which leads to a consequent increase of cyclic adenosine monophosphate (cAMP) within inflammatory cells. This action helps reduce inflammation in the lungs.
3. **Date of registration:** 31/01/25
4. **Date of renewal/reregistration:** 30/01/2030

1.1 Medicine Details

1.1.1 **Registration Number**: 2025/22.1.1/6834
1.1.2 **Pharmacological Classification**: 22.1.1 systemic bronchodilators.
1.1.3 **Category for Distribution**: Prescription Preparations (P.P.).
1.1.4 **Country of Origin**: India

1.2 Information for Users

1.2.1 **Visual Description:** White to off-white, round, flat bevel-edged tablets, debossed with 'H' on one side and 'T' on the other side.
1.2.2 **Primary Packing Material**: Alu-PVC/PVdC blister pack.
1.2.3 **Secondary Packing Materials**: Carton.
1.2.4 **Pack size(s)**: 1×10's and 1×15's.
1.2.5 **Shelf-life and Storage Condition**: 36 months when stored below 30°C in an Alu-PVC/PVdC blister pack.
1.2.6 **Route of Administration**: Oral.
1.2.7 **Therapeutic Indications**: Roflumilast tablets are indicated for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (FEV1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add-on to bronchodilator treatment.

2.0 Scientific Discussion

2.1 Quality Aspects

2.1.1 Quality of Active Pharmaceutical Ingredient(s) (API):

2.1.1.1 **General Properties:** Roflumilast is described as a light brown to white colour crystalline powder. It has an average weight of 403.21g/mol.
2.1.1.2 **Manufacture:** Compliant with GMP standards.

2.1.1.3 **Stability and Container Closure System:** A retest period of 36 months is approved for clobazam when packed in double polyethylene bags placed in a fibreboard drum or HDPE container with tamper-evident sealing below 25°C.

2.1.2 Quality of the Finished Pharmaceutical Product (FPP):

2.1.2.1 **Formulation:** The formulation includes roflumilast as the active ingredient. The excipients used include lactose monohydrate, microcrystalline cellulose, macrogol, magnesium stearate, povidone, and hypromellose.

2.1.2.2 **Manufacture:** Hetero Labs Limited, Unit III, 22-110, IDA, Jeedimetla, Hyderabad, Telangana, India. The site is GMP compliant.

2.1.2.3 **Stability and Container Closure System:** Shelf life of 36 months when stored below 30°C in an Alu-PVC/PVdC blister pack.

2.2 Non-Clinical Aspects

2.2.1 This medicine is a generic formulation of Daliresp 500mcg tablets. Reference is made to the preclinical data obtained with the innovator medicine. Based on this data, no further non-clinical studies are required.

2.3 Clinical Aspects

2.3.1 Roflumilast 250 mcg tablets (Flairof) has a proven pharmaceutical quality and is a generic form of Daliresp 500mcg tablets, a well-known medicinal product with an established favorable efficacy and safety profile. Bioequivalence has been demonstrated with the innovator product.

3.0 Overall benefit/risk assessment and conclusion

3.1 Benefit-Risk Analysis: Roflumilast 250 mcg tablets (Flairof) is a generic medicine that has met the acceptable minimum quality standards and is bioequivalent to the reference medicine. Therefore, its benefits and risks are considered to be the same as those of the reference medicine.

3.2 Conclusion: The Registration Committee registered roflumilast 250 mcg tablets (Flairof) based on a favourable benefit/risk balance.

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The revision date corresponds to that of the original Zimbabwe Public Assessment Report. This document reflects the data available at the time of product registration and will not be updated

with new information related to the product's quality, efficacy, or safety. Please contact us at mcaz@mcaz.co.zw for feedback and inquiries regarding this ZimPAR.