

**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](http://gov.uk/mhra)

## **Decision Cover Letter**

### **Decision of the licensing authority to:**

grant a product specific waiver

MHRA-102399-PIP01-26

### **Scope of the Application**

#### **Active Substance(s)**

TACROLIMUS MONOHYDRATE

#### **Condition(s)**

Treatment of ulcerative colitis

#### **Pharmaceutical Form(s)**

Powder for rectal suspension

#### **Route(s) of Administration**

RECTAL USE

#### **Name / Corporate name of the PIP applicant**

Accord Healthcare Limited

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, Accord Healthcare Limited submitted to the licensing authority on 11/03/2026 10:41 GMT an application for a Waiver

The procedure started on 20/03/2026 14:48 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to grant a product specific waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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## Final Decision Letter

MHRA-102399-PIP01-26

Of 24/04/2026 18:32 BST

On the adopted decision for TACROLIMUS MONOHYDRATE (MHRA-102399-PIP01-26) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for TACROLIMUS MONOHYDRATE, Powder for rectal suspension , RECTAL USE .

This decision is addressed to Accord Healthcare Limited, Sage House 319, Pinner Road, Middlesex, North Harrow, UNITED KINGDOM, HA1 4HF

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of ulcerative colitis The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Powder for rectal suspension Route(s) of administration: RECTAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Not Applicable

**2.2 Indication(s) targeted by the PIP:**

Not Applicable
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**2.3 Subset(s) of the paediatric population concerned by the paediatric development:**

Not Applicable
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**2.4 Pharmaceutical Form(s):**

Not Applicable
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**2.5 Studies:**

<b>Study Type</b>	<b>Number of Studies</b>	<b>Study Description</b>
<b>Quality Measures</b>		
<b>Non-Clinical Studies</b>		
<b>Clinical Studies</b>		
<b>Extrapolation, Modeling &amp; Simulation Studies</b>		
<b>Other Studies</b>		
<b>Other Measures</b>		

**3. Follow-up, completion and deferral of a PIP:**

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	
<b>Date of completion of the paediatric investigation plan:</b>	
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	