

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

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

## **Decision Cover Letter**

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

grant a product specific waiver

MHRA-101816-PIP01-25

### **Scope of the Application**

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

Nipocalimab

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

Prevention of foetal and neonatal alloimmune thrombocytopenia

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

Concentrate for solution for infusion

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

INTRAVENOUS USE

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

Janssen-Cilag Limited

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

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 14/02/2025 16:26 GMT an application for a Waiver

The procedure started on 17/03/2025 15:17 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.

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

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

## Final Decision Letter

MHRA-101816-PIP01-25

Of 09/06/2025 08:30 BST

On the adopted decision for Nipocalimab (MHRA-101816-PIP01-25) 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 Nipocalimab , Concentrate for solution for infusion ,  
INTRAVENOUS USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way, Buckinghamshire, High Wycombe, UNITED KINGDOM, HP12 4EG

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Prevention of foetal and neonatal alloimmune thrombocytopenia (FNAIT) 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): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: For males from birth to less than 18 years of age and pre-menarche female paediatric subjects: - on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). For post-menarche females less than 18 years of age: - 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

**2.3 Subset(s) of the paediatric population concerned by the paediatric development:**

Not Applicable

**2.4 Pharmaceutical Form(s):**

Not Applicable

**2.5 Studies:**

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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

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

