

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

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## **Decision Cover Letter**

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

grant a product specific waiver

MHRA-100326-PIP01-21

### **Scope of the Application**

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

GEMCITABINE HYDROCHLORIDE

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

Treatment of urothelial carcinoma

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

All pharmaceutical forms

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

All routes of administration.

### **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 12/11/2021 13:19 GMT an application for a Waiver

The procedure started on 29/07/2022 15:59 BST

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-100326-PIP01-21

Of 24/08/2022 15:38 BST

On the adopted decision for GEMCITABINE HYDROCHLORIDE (MHRA-100326-PIP01-21) 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 GEMCITABINE HYDROCHLORIDE, All pharmaceutical forms , All routes of administration .

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

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of urothelial carcinoma 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): All pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: 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).

### 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:**

| <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>           |  |