

# Medicines and Healthcare products Regulatory Agency

## REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

### Registrant Details

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|---|--|
| 1. Registration Number  | UK API 25823   |
| 2. Name or corporate name of registrant   | AMICUS THERAPEUTICS UK LIMITED   |
| 3. Permanent or legal address of registrant   | AMICUS THERAPEUTICS UK LIMITED, 1 GLOBESIDE, GLOBESIDE<br>BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1HZ, UNITED<br>KINGDOM |
| 4. Address(es) of site(s) where registered activities<br>take place   | AMICUS THERAPEUTICS UK LIMITED, 1 GLOBESIDE, GLOBESIDE<br>BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1HZ, UNITED<br>KINGDOM |
| 5. National legal basis of registration   | Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)  |
| 6. Name of responsible officer of the competent<br>authority of the member state validating the<br>registration | Confidential   |
| 7. Date   | 04/04/2025   |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

### SCOPE OF REGISTRATION

#### Name and address of the site

**AMICUS THERAPEUTICS UK LIMITED**, 1 GLOBESIDE, GLOBESIDE BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1HZ,  
UNITED KINGDOM

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

##### Active Substance

MIGALASTAT  
HYDROCHLORIDE  
(2000009471)

##### 3rd Country Manufacturer

**CARBOGEN AMCIS AG**, HAUPTSTRASSE  
171, BUBENDORF, CH-4416, SWITZERLAND

##### 3rd Country Distributor

**CARBOGEN AMCIS AG**, HAUPTSTRASSE  
171, BUBENDORF, CH-4416, SWITZERLAND

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

B

Distribution

MIGALASTAT HYDROCHLORIDE (2000009471)