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

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 BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1HZ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	AMICUS THERAPEUTICS UK LIMITED, 1 GLOBESIDE, GLOBESIDE BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1HZ, UNITED 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 authority of the member state validating the registration	Confidential
7. Date	16/10/2024

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	3rd Country Manufacturer	3rd Country Distributor
MIGALASTAT HYDROCHLORIDE (2000009471)	**CARBOGEN AMCIS AG**, HAUPTSTRASSE 171, BUBENDORF, CH-4416, SWITZERLAND	**CARBOGEN AMCIS AG**, HAUPTSTRASSE 171, BUBENDORF, CH-4416, SWITZERLAND

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B   Distribution

MIGALASTAT HYDROCHLORIDE (2000009471)

Issue Date: 16 Oct 2024