

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 57072 |
| 2. Name or corporate name of registrant | KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED |
| 3. Permanent or legal address of registrant | KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED, 3 GALABANK
BUSINESS PARK, QUEEN STREET, GALASHIELS, TD1 1QH, UNITED
KINGDOM |
| 4. Address(es) of site(s) where registered activities
take place | KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED, 3 GALABANK
BUSINESS PARK, QUEEN STREET, GALASHIELS, TD1 1QH, 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 | 12/05/2026 |

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

KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED, 3 GALABANK BUSINESS PARK, QUEEN STREET, GALASHIELS, TD1 1QH, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- | | |
|---|--------------------------------|
| B | Distribution |
| | NALOXEGOL OXALATE (2000016379) |