

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 32301 |
| 2. Name or corporate name of registrant | EISAI MANUFACTURING LIMITED |
| 3. Permanent or legal address of registrant | EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE,
MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE,
MOSQUITO WAY, HATFIELD, AL10 9SN, 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 | 13/08/2025 |

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

EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
LEMBOREXANT (1000018773)	EISAI CO LIMITED , 22 SUNAYAMA, KAMISU-SHI, IBARAKI, JP-314-0255, JAPAN SUMITOMO CHEMICAL COMPANY, LIMITED , C/O CHEMICAL GIFU PLANT 3750, AZAJUHACHICHO MAKI, ANPACHI-CHO, ANPACHI-GUN, GIFU, JP-503-0125, JAPAN	EISAI CO LIMITED , 22 SUNAYAMA, KAMISU-SHI, IBARAKI, JP-314-0255, JAPAN

PERAMPANEL
(3000013362)

EISAI CO LIMITED, 22 SUNAYAMA, KAMISU-SHI, IBARAKI,
JP-314-0255, JAPAN

F.I.S. FABBRICA ITALIANA SINTETICI SPA, VIALE MILANO
26, MONTECCHIO MAGGIORE VICENZA, I-36075, ITALY

EISAI CO LIMITED, 22
SUNAYAMA, KAMISU-SHI,
IBARAKI, JP-314-0255, JAPAN

DONEPEZIL
HYDROCHLORIDE
(2000005638)

EISAI CO LIMITED, 22 SUNAYAMA, KAMISU-SHI, IBARAKI,
JP-314-0255, JAPAN

EISAI CO LIMITED, 4-6-10
KOISHIKAWA, BUNYO-KU,
TOKYO, JP-112-8088, JAPAN