

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 42956
2. Name of Authorisation Holder	THERAKOS (UK) LIMITED
3. Legally registered address of Authorisation Holder	THERAKOS (UK) LIMITED, 3 LOTUS PARK, THE CAUSEWAY, STAINES-UPON-THAMES, TW18 3AG, UNITED KINGDOM
4. Address(es) of Site(s)	THERAKOS (UK) LIMITED, 3 LOTUS PARK, THE CAUSEWAY, STAINES-UPON-THAMES, TW18 3AG, UNITED KINGDOM
5. Scope of authorisation (complete for each site under 4)	ANNEX 1
6. Legal basis of authorisation	Regulation 18 of the Human Medicines Regulations 2012
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	Confidential
8. Date	12/06/2024
9. Annexes attached	Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 Additional provisions

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

THERAKOS (UK) LIMITED, 3 LOTUS PARK, THE CAUSEWAY, STAINES-UPON-THAMES, TW18 3AG, UNITED KINGDOM

1. MEDICINAL PRODUCTS

1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.4 Other Products

The activities performed at the site includes the procurement and supply of medicinal product. The product Uvadex (including UK Product Licence No. PL42956/0001) is a terminally sterilized aqueous formulation of methoxsalen.

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines