

Appendix 5 Risk Assessment Form for an Unlicensed Medicine (To be completed by Pharmacy)

Name	Acarizax	Supplier	ALK-Abello A/S	Strength	12 SQ-HDM
Manufacturer	ALK- Abello A/S	Brand Name	Acarizax	Pack Size	30 units
Licence No.	PA1255/010/001	Country of Origin	Denmark/Spain	Supplier	XXXXXXXXXX
Supplier					Score
MHRA licensed importer					1
NHS Specials Unit					2
Commercial Specials Manufacturer (UK)					2
Supplier not Manufacturer (e.g. Wholesaler)					3
Origin					
UK Manufacturer with Specials Licence					1
EU / USA / Canada / NZ / Australia / Japan + Licensed in country of origin					1
UK Manufacturer - Specials licence but under Section 10 exemption					4
Elsewhere - Licensed in country of origin					HIGH
EU / USA / Canada / NZ / Australia / Japan + Unlicensed in country of origin					HIGH
Certification					
Fully licenced product with EMEA / Licence number (imports)					1
Certificate of Analysis and GMP compliance available					1
Certificate of Conformity + product analysis					2
Certificate of Conformity - no product analysis					3
No Certificate available					4
TSE Documentation (not required for EU Licenced Products)					n/a
Product TSE compliance certification					0
No TSE compliance certification					HIGH
Packaging and Labelling					
English					0
Foreign Language: Over labelled in English + translated SPC/PIL					3
Foreign Language					HIGH
Specification (not required if product is licenced or comprehensive Certificate of Analysis provided)					
Manufacturer's specification available					0
No external specification available					HIGH
Route of Administration					
Topical to intact skin (non-sterile)					0
Mucous membranes, broken skin, oral (non-sterile)					1
Sterile all routes except intrathecal / intravitreal					2
Sterile intrathecal or intravitreal					3
Therapeutic Agent (Clinical Input)					
Established Therapeutic agent - no special problems					0
Recognised therapeutic agent - minor problems or little experience					2
Novel Therapeutic agent of unusual use					4
Unrecognised therapeutic agent with some supporting info					6
Unrecognised therapeutic agent with no supporting info					HIGH
Recognised therapeutic agent with known problems					HIGH
Product containing material of animal or human origin					HIGH
Risk Category					
Low	3 to 7	4	Additional Local Controls		Final Risk Category
Medium	8 to 14				
High	14+				
JAC updated					Low
<input type="checkbox"/>			Print	Sign	Date
Risk Category Signed off by					
Regional QA Verification					
Entered onto Database					