

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Denmark	Omrrix Biopharmaceuticals S.A., Chaussee de Waterloo 200, B-1640 Rhode-St-Genese Belgium	Quixil	Fibronectin, human: 30 mg Human fibrinogen: 30 mg Arginine hydrochloride 19 mg Acidum tranexamicum 95 mg Glycine 7,9 mg Sodium chloride 7 mg	Solution for sealant	Intralesional use
France	OMRIX Biopharmaceuticals S.A. Chaussée de Waterloo 200 1640 Rhode-St-Genèse Belgium	QUIXIL solution for sealant	1st Component (BAC) Fibrinogen-Fibronectin 40 mg/ml - 60mg/ml Tranexamic acid 85 mg/ml -105mg /ml 2nd Component (Thrombin) Thrombin 800 IU /ml - 1200 IU /ml Calcium chloride: 5,6 mg/ml - 6,2 mg /ml	Solution for sealant	Epileisional use
Italy	OMRIX Biopharmaceuticals S.A. Chaussée de Waterloo 200 1640 Rhode-St-Genèse Belgium	QUIXIL	Fibrinogen and Fibronectin: 40 mg/ml - 60 mg/ml Tranexamic acid: 85 mg/ml -105 mg/ml Thrombin: 800 IU/ml -1,200 IU/ml Calcium Chloride: 5.6 mg/ml – 6.2 mg/ml	Solution for sealant	Epileisional use
United Kingdom	Omrrix Biopharmaceuticals S.A., Chaussee de Waterloo 200, B-1640 Rhode-St-Genese Belgium	Quixil	Clottable protein conc: 50mg/ml Thrombin: 1000 IU/ml Calcium chloride: 5.9 mg/ml Tranexamic acid: 95mg/ml	Solution for sealant	Epileisional use