



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 January 2018  
EMA/24042/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: fluorescein (systemic use)

Procedure no.: PSUSA/00009153/201704

---

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Fluorescein Théa 500 mg/5 ml solution fort injection	not available	20010285	SERB SA	BG
FLUORESCEINE SODIQUE FAURE 10 POUR CENT, solution injectable	not available	319028-3	SERB SA	FR
FLUORESCEINE SODIQUE FAURE 10 POUR CENT, solution injectable	not available	320337-6	SERB SA	FR
Fluorescéine 10 % Faure solution injectable	not available	201130045	SERB SA	LU
FLUORESCEINE 10% Faure solution injectable	not available	BE162811	SERB SA	BE
FLUORESCEINE 10% Faure oplossing voor injectie	not available	BE162811	SERB SA	BE
FLUORESCEINE 10% Faure Injektionlösung	not available	BE162811	SERB SA	BE
Anatera 100 mg/ml solution for injection	DE/H/0746/001	PL 00101/0989	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Fluorescite 100 mg/ml oldatos injekció	not available	OGYI-T- 20 618/01	ALCON HUNGARIAN LTD.	HU
Fluorescite 100 mg/ml solução injectável	DE/H/0746/001	5021464	ALCON PORTUGAL - PRODUTOS E EQUIPAMENTOS OFTALMOLÓGICOS, LDA.	PT
FLUORESCITE 100 mg/ml injekcinis tirpalas	DE/H/0746/001	LT/1/07/0735/001	SA ALCON-COUVREUR NV	LT
Fluorescite 100 mg/ml süstelahus	DE/H/0746/001	542107	SA ALCON-COUVREUR NV	EE
Fluorescite 100 mg/ml škidums injekcijam	DE/H/0746/001	07-0131	SA ALCON-COUVREUR NV	LV

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Fluorescite, 100 mg/ml, roztwór do wstrzykiwań	DE/H/0746/001	12952	ALCON POLSKA SP. Z.O.O	PL
Fluorescein Sodium 100 mg/ml, Solution for Injection	not available	PL 43956/0002	SERB SA	UK
Fluoresceína SERB 100 mg/ml solução injectável	not available	4017885	SERB SA	PT
Fluoresceína SERB 100 mg/ml solução injectável	not available	4017984	SERB SA	PT
FLUOCYNE 10%, solution injectable I.V.	not available	369 542-2	SERB	FR
FLUOCYNE 10%, solution injectable I.V.	not available	365 669-8	SERB	FR
FLUOCYNE 10%, solution injectable I.V.	not available	367 517-0	SERB	FR
FLUOCYNE 10%, solution injectable I.V.	not available	566 130-9	SERB	FR
Fluoresceína Oculos 10%, solución inyectable	not available	65.458	SERB SA	ES
Fluoresceína Oculos 10%, solución inyectable	not available	65.458	SERB SA	ES
Fluoresceine SERB 100 mg/ml (10%), roztwór do wstrzykiwan	not available	POZWOLENIE NR R/2896	SERB SA	PL
Fluorescein SERB 100 mg/ml oldatos injekció	not available	OGYI-T-1675/01	SERB SA	HU