

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 EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Lundbeck Austria GmbH Dresdner Strasse 82 1200 Vienna Austria	Saroten	10 mg	Film-coated tablet	Oral use	
Austria	Lundbeck Austria GmbH Dresdner Strasse 82 1200 Vienna Austria	Saroten	25 mg	Film-coated tablet	Oral use	
Austria	Lundbeck Austria GmbH Dresdner Strasse 82 1200 Vienna Austria	Saroten Retard	25 mg	Prolonged-release capsule, hard	Oral use	
Austria	Lundbeck Austria GmbH Dresdner Strasse 82 1200 Vienna Austria	Saroten Retard	50 mg	Prolonged-release capsule, hard	Oral use	
Belgium	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex	10 mg	Film-coated tablet	Oral use	
Belgium	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex	25 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Belgium	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex Diffucaps	25 mg	Prolonged-release capsule, hard	Oral use	
Belgium	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex Diffucaps	50 mg	Prolonged-release capsule, hard	Oral use	
Cyprus	C. G. Papaloisou Ltd. Office address: 35 Kilkis Avenue 2234 Latsia Cyprus Mail address: P.O. Box 1711 2261 Latsia Cyprus	Saroten Retard	25 mg	Prolonged-release capsule, hard	Oral use	
Cyprus	C. G. Papaloisou Ltd. Office address: 35 Kilkis Avenue 2234 Latsia Cyprus Mail address: P.O. Box 1711 2261 Latsia Cyprus	Saroten Retard	50 mg	Prolonged-release capsule, hard	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Denmark	H. Lundbeck A/S Ottoliavej 9 2500 Valby Denmark	Saroten	10 mg	Film-coated tablet	Oral use	
Denmark	H. Lundbeck A/S Ottoliavej 9 2500 Valby Denmark	Saroten	25 mg	Film-coated tablet	Oral use	
Denmark	H. Lundbeck A/S Ottoliavej 9 2500 Valby Denmark	Saroten Retard	25 mg	Prolonged-release capsule, hard	Oral use	
Denmark	H. Lundbeck A/S Ottoliavej 9 2500 Valby Denmark	Saroten Retard	50 mg	Prolonged-release capsule, hard	Oral use	
Estonia	H. Lundbeck A/S Ottoliavej 9 2500 Valby Denmark	Saroten Retard	50 mg	Prolonged-release capsule, hard	Oral use	
Germany	Bayer Vital GmbH Medizin/Zulassung 51368 Leverkusen Germany	Saroten Tabs	50 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Bayer Vital GmbH Medizin/Zulassung 51368 Leverkusen Germany	Saroten retard Tabs	75 mg	Modified-release tablet	Oral use	
Germany	Bayer Vital GmbH Medizin/Zulassung 51368 Leverkusen Germany	Saroten 2 ml	50mg/2ml	Solution for injection	Intramuscular use intravenous use	25 mg/ml
Greece	PNG GEROLYMATOS MEDICAL AE, ASKLIPIOU 13, KRYONERI 14568	SAROTEN	25 mg	Modified-release capsule, hard	Oral use	
Greece	PNG GEROLYMATOS MEDICAL AE, ASKLIPIOU 13, KRYONERI 14568	SAROTEN	75 mg	Modified-release capsule, hard	Oral use	
Greece	PNG GEROLYMATOS MEDICAL AE, ASKLIPIOU 13, KRYONERI 14568	SAROTEN	25 mg	Coated tablet	Oral use	
Greece	PNG GEROLYMATOS MEDICAL AE, ASKLIPIOU 13, KRYONERI 14568	SAROTEN	10 mg	Coated Tablet	Oral use	
Luxembourg	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex	10 mg	Film-coated tablet	Oral use	
Luxembourg	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex	25 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Luxembourg	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex Diffucaps	25 mg	Prolonged-release capsule, hard	Oral use	
Luxembourg	Lundbeck S.A. Avenue Molière 225 1050 Brussels Belgium	Redomex Diffucaps	50 mg	Prolonged-release capsule, hard	Oral use	
Netherlands	Lundbeck B.V. Gebouw Jupiter Herikerbergweg 100 Postbus 12021 1100 AA Amsterdam The Netherlands	Sarotex Retard 25	25 mg	Prolonged-release capsule, hard	Oral use	
Netherlands	Lundbeck B.V. Gebouw Jupiter Herikerbergweg 100 Postbus 12021 1100 AA Amsterdam The Netherlands	Sarotex Retard 50	50 mg	Prolonged-release capsule, hard	Oral use	
Norway	H. Lundbeck A/S Ottiliavej 9 2500 Valby Denmark	Sarotex	10 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Norway	H. Lundbeck A/S Ottiliavej 9 2500 Valby Denmark	Sarotex	25 mg	Film-coated tablet	Oral use	
Norway	H. Lundbeck A/S Ottiliavej 9 2500 Valby Denmark	Sarotex Retard	25 mg	Prolonged-release capsule, hard	Oral use	
Norway	H. Lundbeck A/S Ottiliavej 9 2500 Valby Denmark	Sarotex Retard	50 mg	Prolonged-release capsule, hard	Oral use	
Sweden	H. Lundbeck A/S Ottiliavej 9 2500 Valby Denmark	Saroten	10 mg	Film-coated tablet	Oral use	
Sweden	H. Lundbeck A/S Ottiliavej 9 2500 Valby Denmark	Saroten	25 mg	Film-coated tablet	Oral use	