

Annex I

List of medicinal products and presentations

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
France	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 16 mg, comprimé pelliculé ¹	16 mg	film-coated tablet	oral use
France	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 40 mg, comprimé pelliculé ¹	40 mg	film-coated tablet	oral use
France	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 55 mg, comprimé pelliculé ¹	55 mg	film-coated tablet	oral use
France	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 63 mg, comprimé pelliculé ¹	63 mg	film-coated tablet	oral use
France	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 79 mg, comprimé pelliculé ¹	79 mg	film-coated tablet	oral use

¹ Invented name not accepted by National Competent Authority, pending new proposal by the applicant.

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
France	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 111 mg, comprimé pelliculé ²	111 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 16 mg Filmtabletten	16 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 16 mg Filmtabletten	16 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 40 mg Filmtabletten	40 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 40 mg Filmtabletten	40 mg	film-coated tablet	oral use

² Invented name not accepted by National Competent Authority, pending new proposal by the applicant.

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 55 mg Filmtabletten	55 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 55 mg Filmtabletten	55 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 63 mg Filmtabletten	63 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 63 mg Filmtabletten	63 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 79 mg Filmtabletten	79 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 79 mg Filmlabletten	79 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 111 mg Filmlabletten	111 mg	film-coated tablet	oral use
Germany	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 111 mg Filmlabletten	111 mg	film-coated tablet	oral use
Hungary	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 16 mg filmlabletta	16 mg	film-coated tablet	oral use
Hungary	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 40 mg filmlabletta	40 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Hungary	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 55 mg filmtabletta	55 mg	film-coated tablet	oral use
Hungary	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 63 mg filmtabletta	63 mg	film-coated tablet	oral use
Hungary	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 79 mg filmtabletta	79 mg	film-coated tablet	oral use
Hungary	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 111 mg filmtabletta	111 mg	film-coated tablet	oral use
Ireland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 16 mg film-coated tablets	16 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Ireland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 40 mg film-coated tablets	40 mg	film-coated tablet	oral use
Ireland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 55 mg film-coated tablets	55 mg	film-coated tablet	oral use
Ireland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 63 mg film-coated tablets	63 mg	film-coated tablet	oral use
Ireland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 79 mg film-coated tablets	79 mg	film-coated tablet	oral use
Ireland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn 111 mg film-coated tablets	111 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	16 mg	film-coated tablet	oral use
Italy	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	40 mg	film-coated tablet	oral use
Italy	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	55 mg	film-coated tablet	oral use
Italy	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	63 mg	film-coated tablet	oral use
Italy	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	79 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	111 mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	16 mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	40 mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	55 mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	63 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Poland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	79 mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	111 mg	film-coated tablet	oral use
Portugal	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	16 mg	film-coated tablet	oral use
Portugal	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	40 mg	film-coated tablet	oral use
Portugal	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	55 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	63 mg	film-coated tablet	oral use
Portugal	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	79 mg	film-coated tablet	oral use
Portugal	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	111 mg	film-coated tablet	oral use
Romania	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 16 mg comprimate filmate	16 mg	film-coated tablet	oral use
Romania	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 40 mg comprimate filmate	40 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Romania	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 55 mg comprimate filmate	55 mg	film-coated tablet	oral use
Romania	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 63 mg comprimate filmate	63 mg	film-coated tablet	oral use
Romania	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 79 mg comprimate filmate	79 mg	film-coated tablet	oral use
Romania	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 111 mg comprimate filmate	111 mg	film-coated tablet	oral use
Slovak Republic	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 16 mg	16 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 40 mg	40 mg	film-coated tablet	oral use
Slovak Republic	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 55 mg	55 mg	film-coated tablet	oral use
Slovak Republic	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 63 mg	63 mg	film-coated tablet	oral use
Slovak Republic	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 79 mg	79 mg	film-coated tablet	oral use
Slovak Republic	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph 111 mg	111 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	16 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	16 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	40 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	40 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	55 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	55 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	63 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	63 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	79 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	79 mg	film-coated tablet	oral use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Anafezyn	111 mg	film-coated tablet	oral use
Sweden	Zentiva, k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Daruph	111 mg	film-coated tablet	oral use