

## **Annex I**

### **List of nationally authorised medicinal products and marketing authorisation applications**

**Annex IA: Medicinal products recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established**

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Austria	Krka d.d., Novo mesto		Cefuroxim Krka 250mg Filmtabletten	Cefuroxime	250 mg	Film-coated tablet	Oral use
Austria	Krka d.d., Novo mesto		Cefuroxim Krka 500mg Filmtabletten	Cefuroxime	500 mg	Film-coated tablet	Oral use
Bulgaria	Krka d.d., Novo mesto		Furocef 250 mg film-coated tablets	Cefuroxime	250 mg	Film-coated tablet	Oral use
Bulgaria	Krka d.d., Novo mesto		Furocef 500 mg film-coated tablets	Cefuroxime	500 mg	Film-coated tablet	Oral use
Croatia	Krka - farma d.o.o.		Furocef 250 mg film-coated tablets	Cefuroxime	250 mg	Film-coated tablet	Oral use
Croatia	Krka - farma d.o.o.		Furocef 500 mg film- coated tablets	Cefuroxime	500 mg	Film-coated tablet	Oral use
Czech Republic	Krka d.d., Novo mesto		Ricefan 250 mg	Cefuroxime	250 mg	Film-coated tablet	Oral use
Czech Republic	Krka d.d., Novo mesto		Ricefan 500 mg	Cefuroxime	500 mg	Film-coated tablet	Oral use
Estonia	Krka d.d., Novo mesto		FUROCEF	Cefuroxime	250 mg	Film-coated tablet	Oral use
Estonia	Krka d.d., Novo mesto		FUROCEF	Cefuroxime	500 mg	Film-coated tablet	Oral use

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France	Krka d.d., Novo mesto		CEFUROXIME KRKA 250 mg, comprimé pelliculé	Cefuroxime	250 mg	Film-coated tablet	Oral use
France	Krka d.d., Novo mesto		CEFUROXIME KRKA 500 mg, comprimé pelliculé	Cefuroxime	500 mg	Film-coated tablet	Oral use
Germany	Alkem Pharma GmbH		Cefuroxim Alkem 250 mg Filmtabletten	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
Germany	Alkem Pharma GmbH		Cefuroxim Alkem 500 mg Filmtabletten	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use
Hungary	Krka d.d., Novo mesto		Furocef Krka 250 mg tablets	Cefuroxime	250 mg	Tablet	Oral use
Hungary	Krka d.d., Novo mesto		Furocef Krka 500 mg tablets	Cefuroxime	500 mg	Tablet	Oral use
Latvia	Krka d.d., Novo mesto		Ricefan 250 mg film-coated tablets	Cefuroxime	250 mg	Film-coated tablet	Oral use
Latvia	Krka d.d., Novo mesto		Ricefan 500 mg film-coated tablets	Cefuroxime	500 mg	Film-coated tablet	Oral use
Lithuania	Krka d.d., Novo mesto		Ricefan	Cefuroxime	250 mg	Film-coated tablet	Oral use
Lithuania	Krka d.d., Novo mesto		Ricefan	Cefuroxime	500 mg	Film-coated tablet	Oral use
Lithuania		SIA Ingen Pharma	Cefuroxime Ingen Pharma	Cefuroxime	250 mg	Film-coated tablet	Oral use

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Lithuania		SIA Ingen Pharma	Cefuroxime Ingen Pharma	Cefuroxime	500 mg	Film-coated tablet	Oral use
Poland	Krka d.d., Novo mesto		Furocef	Cefuroxime	250 mg	Film-coated tablet	Oral use
Poland	Krka d.d., Novo mesto		Furocef	Cefuroxime	500 mg	Film-coated tablet	Oral use
Portugal	Krka d.d., Novo mesto		Cefuroxima Krka	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
Portugal	Krka d.d., Novo mesto		Cefuroxima Krka	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use
Romania	Krka d.d., Novo mesto		CEFUROXIME KRKA 250 mg, comprimate	Cefuroxime	250 mg	Film-coated tablet	Oral use
Romania	Krka d.d., Novo mesto		CEFUROXIME KRKA 500 mg, comprimate	Cefuroxime	500 mg	Film-coated tablet	Oral use
Slovak Republic	Krka d.d., Novo mesto		Furocef 250 mg filmom obalené tablety	Cefuroxime	250 mg	Film-coated tablet	Oral use
Slovak Republic	Krka d.d., Novo mesto		Furocef 500 mg filmom obalené tablety	Cefuroxime	500 mg	Film-coated tablet	Oral use
Slovenia	Krka d.d., Novo mesto		Ricefan	Cefuroxime	250 mg	Film-coated tablet	Oral use
Slovenia	Krka d.d., Novo mesto		Ricefan	Cefuroxime	500 mg	Film-coated tablet	Oral use

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Spain	Alkem Pharma GmbH		Cefuroxima 500 mg comprimidos recubiertos con película	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use
Spain	Alkem Pharma GmbH		Cefuroxima Alkem 250 mg comprimidos recubiertos con película	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
Spain	Krka d.d., Novo mesto		Cefuroxima KRKA 250 mg comprimidos recubiertos con película	Cefuroxime	250 mg	Film-coated tablet	Oral use
Spain	Krka d.d., Novo mesto		Cefuroxima KRKA 500 mg comprimidos recubiertos con película	Cefuroxime	500 mg	Film-coated tablet	Oral use
United Kingdom	Alkem Pharma GmbH		Cefuroxime 250mg film-coated tablets	Cefuroxime axetil	250 mg	Film-coated tablet	Oral use
United Kingdom	Alkem Pharma GmbH		Cefuroxime 500mg film-coated tablets	Cefuroxime axetil	500 mg	Film-coated tablet	Oral use

**Annex IB: Products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation**

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Czech Republic	Alkem Pharma GmbH		Riluzole Alkem 50 mg potahované tablety	Riluzole	50 mg	Film-coated tablet	Oral use
Denmark		Orion Corporation	Ibuprofen Orion	Ibuprofen	200 mg	Film-coated tablet	Oral use
Denmark		Orion Corporation	Ibuprofen Orion	Ibuprofen	400 mg	Film-coated tablet	Oral use
Denmark		Orion Corporation	Ibuprofen Orion	Ibuprofen	600 mg	Film-coated tablet	Oral use
Germany	Alkem Pharma GmbH		Riluzol Alkem 50 mg Filmtabletten	Riluzole	50 mg	Film-coated tablet	Oral use
Spain	Alkem Pharma GmbH		Riluzole 50 mg comprimidos recubiertos con película EFG	Riluzole	50 mg	Film-coated tablet	Oral use
Sweden		Orion Corporation	Ibuprofen Orion	Ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden		Orion Corporation	Ibuprofen Orion	Ibuprofen	400 mg	Film-coated tablet	Oral use
Sweden		Orion Corporation	Ibuprofen Orion	Ibuprofen	600 mg	Film-coated tablet	Oral use
United Kingdom	Alkem Pharma GmbH		Riluzole alkem 50 mg film-coated tablets	Riluzole	50 mg	Film-coated tablet	Oral use