

## FDF-CTD DOSSIER

INN	Dosage Form	Therapeutic Class	Available Dossier	Reference Product
Acitretin	Capsule 7.5-10-12.5-25 mg	Antipsoriatic	EU-RoW	Soriatane
Clofarabine	Vial-Liquid 20 mg	Antineoplastic	US-EU-RoW	Clolar/Evoltra
Daptomycin	Vial-Lyo 350-500 mg	Antibacterial	US-EU-RoW	Cubicin
Deferoxamine mesylate	Vial-Lyo 500-2,000 mg	Iron chelating agent	US-EU-RoW	Desferal
Lenvatinib mesylate <b>New</b>	Capsule 4-10 mg	Antineoplastic	US-EU-RoW	Lenvima
Nintedanib esylate <b>New</b>	Soft-Gel 100-150 mg	Antineoplastic, IPF	US-EU-RoW	Ofev
Olaparib <b>New</b>	Film-Coated Tablet 100-150 mg	Antineoplastic	US-EU-RoW	Lymparza
Teduglutide <b>New</b>	Vial-Lyo 5 mg	Short Bowel Syndrome (SBS)	US	Gattex
Teriflunomide	Film-Coated Tablet 7-14 mg	Agents for multiple sclerosis	US-EU-RoW	Aubagio
Valgancyclovir	Film-Coated Tablet 450 mg	Antiviral	EU-RoW	Valcyte

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