

Title (en)
MICROEMULSION PRECONCENTRATE CONTAINING CLADRIBINE PARTICULARLY FOR ORAL ADMINISTRATION AND METHOD OF PREPARATION

Title (de)
MIKROEMULSIONSVORKONZENTRAT MIT CLADRIBIN, INSBESONDERE ZUR ORALEN VERABREICHUNG UND HERSTELLUNGSVERFAHREN

Title (fr)
PRÉCONCENTRÉ DE MICROÉMULSION CONTENANT DE LA CLADRIBINE, EN PARTICULIER POUR UNE ADMINISTRATION ORALE ET SON PROCÉDÉ DE PRÉPARATION

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Application
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Priority
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Abstract (en)
[origin: WO2022156836A1] The invention relates to an anhydrous microemulsion preconcentrate containing cladribine, comprising: cladribine dissolved in at least one aprotic polar solvent and in at least one auxiliary organic solvent having an acceptable affinity for water, a mixture of a non-ionogenic surfactant having a hydrophilic-lipophilic equilibrium > 10 with a non-ionogenic water-insoluble surfactant having a hydrophilic-lipophilic equilibrium < 10 and/or with lipophilic vehicles containing a high proportion of long-chain fatty acids, such as, e.g. Glycerol mono-oleate or glycerol mono-linoleate. The hydrophilic and hydrophobic components are mixed to form a homogeneous mixture. This homogeneous mixture is then mixed with a cladribine solution to produce a formulation which, when introduced into the gastrointestinal tract, spontaneously forms a dispersion of non-ionogenic surfactant nanoparticles containing dissolved cladribine molecules.

IPC 8 full level
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