PASS Information (Synopsis)

Dear Prescriber, this is to inform you Tillomed Laboratories is conducting a Cidofovir PASS study, details of which can be found below.

If you are interested in participating in the Cidofovir Exposure Study, please visit the website www.cidofovir.com

The Prescribers' Guide will provide you with further detailed information about the Cidofovir Exposure Study and can be found on the website. Please download the Patient Information Sheet and Informed Consent Form for completion by each Patient and upload to the website. Patient specific Unique Study Reference Numbers will then be issued to you to enable you to complete a baseline data form and follow-up forms for each Patient.

Title	Cidofovir Exposure Study
Synopsis version identifier	Version 2.0
Date of last version of synopsis	1st November 2018
Synopsis number	EMC00001
Active substance	Cidofovir (ATC code: J05AB12; Pharmacotherapeutic Group: antivirals for systemic use)
Medicinal product	Cidofovir Emcure Pharma 75 mg/ml Concentrate for Solution for Infusion
Product reference	Vistide®
Procedure number	DE/H/6139/001/DC
Joint PASS	Yes

Research objectives	The objectives of the study are: ▪ To identify the indications and patient populations for Cidofovir use; ▪ To evaluate patterns and compare rates of adverse events occurring in the on-label group with events occurring in the off -label group ▪ To assess patient outcome following treatment in specified indication; (*Based on the data accumulated a comparison of AE type and rate using the "on-label" patient group as comparator will be considered for analysis*)
Countries of study	United Kingdom, Germany, Belgium and Spain.

Marketing authorisation holders

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