PASS Information (Synopsis)

Title	Cidofovir Exposure Registry Study
Protocol version identifier	Version 1.0
Date of last version of protocol	Not applicable
EU PAS register number	
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	UK/H/5536/001/DC
Marketing authorisation holder(s)	Emcure Pharma UK Ltd.
Joint PASS	No
Research question and 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 would be considered for analysis*)
Country (-ies) of study	United Kingdom, Germany, Belgium and Spain.

Marketing authorization holder(s)

Marketing authorisation holder	**Emcure Pharma UK Ltd.** 3 Howard Road Eaton Socon, St Neots Cambridgeshire PE19 8ET United Kingdom
MAH contact person(s)	●Ms Charlene Senanayake, Deputy Manager - RA & QA ●Mrs Sharan Patel Manager – QA & PV Emcure Pharma UK Ltd Basepoint Business Centre 110 Butterfield, Great Marlings Luton Bedfordshire LU2 8DL Charlene.S@emcure.co.in Sharan.Patel@emcure.co.in Tel: +44 (0) 1582 434232 : Fax: +44 (0) 20 80431818

Should you be interested in participating in the Cidofovir Exposure Registry, please visit the website www.cidofovir.eu

The Prescribers guide will provide you further detailed information on the Cidofovir Exposure Registry which can be found on the website. Kindly download the Informed Consent Document for completion and upload back on to the website, in order to be issued a patient specific username and password which can be used to login using the website. After login, the physician will be able to complete the Baseline Data Form and Follow-up Form's for that patient.

For any further assistance for the log-in, please contact Emcure Pharma UK Ltd, Pharmacovigilance department on: +44 (0) 1582 434232Email: cidofovir-pass@emcure.co.in