ICH E2B

ADVERSE EVENT FORM

N.1.1 Type of Messages in Batch	ichicsr	N.1.2 Batch Number	CASE-SV-00073-Adverse Event-001-20250710045404
N.1.3 Batch Sender Identifier	OGMILAM	N.1.4 Batch Receiver Identifier	LCMERCK
N.1.5 Date of Batch Transmission		20250710045100	

N.2.r ICH ICSR Message Header

N.2.r.1 Message Identifier	V3R0000000GN004	N.2.r.4 Date of Message Creation	20250710045100
N.2.r.2 Message Sender Identifier	OGMILAM	N.2.r.3 Message Receiver Identifier	LCMERCK

C.1 IDENTIFICATION OF THE CASE SAFETY REPORT

C.1.1 Sender's (case) Safety Report Unique Identifier CASE-SV-00073-Adverse Event-001		C.1.3 Type of Report Spontaneous(1)
C.1.2 Date of Creation 20250710045100	C.1.4 Date Report Was First Received from Source 20250709	C.1.5 Date of Most Recent Information for This Report 20250710
C.1.6.1 Are Additional Documents Available?		C.1.7 Does This Case Fulfil the Local Criteria for an Expedited Report?
C.1.8.1 Worldwide Unique Case Identification Number	C.1.8.2 First Sender of This Case	C.1.9.1 Other Case Identifiers in Previous Transmissions
C.1.11.1 Report Nullification/Amendment		C.1.11.2 Reason for Nullification/Amendment

C.1.6 Additional Available Documents Held by Sender - Header

C.1.6.1.r.1 Documents Held by Sender
CILOSTAZOL.png

C.1.6.1.r.2 Included Documents
Media Type : image/png
Representation : B64

C.1.6.1.r.1 Documents Held by Sender
CILOSTAZOL NIÑOS.pdf

C.1.6.1.r.2 Included Documents
Media Type : application/pdf
Representation : B64

C.2.R PRIMARY SOURCE(S) OF INFORMATION

C.2.r.1.1 Reporter's Title	C.2.r.1.2 Reporter's Given Name ME	C.2.r.1.3 Reporter's Middle Name
C.2.r.1.4 Reporter's Family Name MV	C.2.r.2.1 Reporter's Organisation	C.2.r.2.2 Reporter's Department
C.2.r.2.3 Reporter's Street Not Asked		C.2.r.2.4 Reporter's City Not Asked
C.2.r.2.5 Reporter's State or Province Not Asked	C.2.r.2.6 Reporter's Postcode Not Asked	C.2.r.3 Reporter's Country Code EL SALVADOR(SV)
C.2.r.2.7 Reporter's Telephone Not Asked	C.2.r.4 Qualification Physician(1)	C.2.r.5 Primary source for regulatory purposes Yes(1)

C.3 INFORMATION ON SENDER OF CASE SAFETY REPORT

C.3.1 Sender Type	C.3.2 Sender Organization	C.3.3.1 Sender's Department
C.3.3.2 Sender's Title	C.3.3.3 Sender's Given Name	C.3.3.4 Sender's Middle Name
C.3.3.5 Sender's Family Name	C.3.4.1 Sender's Street Address	C.3.4.2 Sender's City
C.3.4.3 Sender's State or Province	C.3.4.4 Sender's Postcode	C.3.4.5 Sender's Country Code
C.3.4.6 Sender's Telephone	C.3.4.7 Sender's Fax	C.3.4.8 Sender's E-mail Address

C.5 STUDY IDENTIFICATION

C.5.2 Study Name

C.5.3 Sponsor Study Number	C.5.4 Study Type Where Reaction(s)/Event(s) Were Observed
FDA.C.5.5a IND Number where AE Occurred	FDA.C.5.5b PANDA Number where AE Occurred

D. PATIENT CHARACTERISTICS

D.1 Patient (name or initials) unknown	D.1.1.1 Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)	D.1.1.2 Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)
D.1.1.3 Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)	D.1.1.4 Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)	D.3 Body Weight (kg)

D.4 Height (cm)	D.5 Sex	D.6 Last Menstrual Period Date
D.7.2 Text for Relevant Medical History and Concurrent Conditions (not including reaction / event) Unknown		D.9.1 Date of Death
D.7.3 Concomitant Therapies		D.9.3 Was Autopsy Done?

D.2 Age Information

D.2.1 Date of Birth	D.2.2a Age at Time of Onset of Reaction /Event (number) 10	D.2.2b Age at Time of Onset of Reaction /Event (unit) Year(s)(a)
D.2.3 Patient Age Group (as per reporter) Child(3)	D.2.2.1aGestation Period When Reaction / Event Was Observed in the Foetus (number)	D.2.2.1b Gestation Period When Reaction/Event Was Observed in the Foetus (unit)

E.i REACTION(S) / EVENT(S)

E.i.1.1a Reaction /Event as Reported by the Primary Source in Native Language		
E.i.1.1b Reaction /Event as Reported by the Primary Source Language	E.i.1.2 Reaction /Event as Reported by the Primary Source for Translation	
E.i.2.1a MedDRA version for reaction/event	E.i.2.1b Reaction /Event (MedDRA code)	E.i.3.1 Term highlighted by the reporter
E.i.3.2 Seriousness Criteria at Event Level (more than one can be chosen) E.i.3.2a Results in Death E.i.3.2b Life Threatening E.i.3.2c Caused /Prolonged Hospitalisation E.i.3.2d Disabling /Incapacitating E.i.3.2e Congenital Anomaly /Birth Defect E.i.3.2f Other Medically Important Condition	E.i.4 Date of start of reaction/event E.i.6a Duration of Reaction /Event (number) E.i.7 Outcome of reaction/event at the time of last observation Unknown(0)	E.i.5 Date of End of Reaction /Event E.i.6b Duration of Reaction / Event (unit) E.i.8 Medical Confirmation by Healthcare Professional
E.i.9 Identification of the Country Where the Reaction /Event Occurred EL SALVADOR(SV)		

G.k DRUG(S) INFORMATION

G.k.1 Characterization of Drug Role Suspect(1)	
G.k.2.1.1a MPID Version Date / Number	G.k.2.1.1b Medicinal Product Identifier (MPID)
G.k.2.1.2a PhPID Version Date / Number	G.k.2.1.2b Pharmaceutical Product Identifier (PhPID)

G.k.2.2 Medicinal Product Name as Reported by the Primary Source cilostazol	G.k.2.4 Identification of the Country Where the Drug Was Obtained
G.k.2.2.EU.1 Invented name	
G.k.2.2.EU.2 Scientific name	
G.k.2.2.EU.3 Trademark name	
G.k.2.2.EU.4 Strength name	
G.k.2.2.EU.5 Form name	
G.k.2.2.EU.6 Container name	
G.k.2.2.EU.7 Device name	
G.k.2.2.EU.8 Intended use name	

G.k.2.5 Investigational Product Blinded	G.k.3.1 Authorisation /Application Number	G.k.3.2 Country of Authorisation / Application
G.k.3.3 Name of Holder /Applicant	G.k.5a Cumulative Dose to First Reaction (number)	G.k.5b Cumulative Dose to First Reaction (unit)
G.k.6a Gestation Period at Time of Exposure (number)	G.k.6b Gestation Period at Time of Exposure (unit)	G.k.8 Action(s) Taken with Drug
G.k.11 Additional Information on Drug (free text)		

G.k.2.2.EU.9.r Device component

G.k.2.2.EU.9.r.1 Device Component name		
G.k.2.2.EU.9.r.2 Device Component TermID version Date/Number		
G.k.2.2.EU.9.r.3 Device Component TermID		
G.k.2.2.EU.9.r.4 Device Batch Lot number		
G.k.4.r Dosage and Relevant Information		
G.k.4.r.1a Dose (number)	G.k.4.r.1b Dose (unit)	G.k.4.r.2 Number of Units in the Interval
G.k.4.r.3 Definition of the Time Interval Unit	G.k.4.r.4 Date and Time of Start of Drug	G.k.4.r.5 Date and Time of Last Administration
G.k.4.r.6a Duration of Drug Administration (number)	G.k.4.r.6b Duration of Drug Administration (unit)	G.k.4.r.7 Batch /Lot Number unknown
G.k.4.r.8 Dosage Text		
G.k.4.r.9.1 Pharmaceutical Dose Form (free text)		G.k.4.r.9.2a Pharmaceutical Dose Form TermID Version Date/Number
G.k.4.r.9.2b Pharmaceutical Dose Form Term ID		G.k.4.r.10.1 Route of Administration (free text)
G.k.4.r.10.2a Route of Administration TermID Version Date /Number		G.k.4.r.10.2b Route of Adminstration Term ID
G.k.4.r.11.1 Parent Route of Administration (free text)	G.k.4.r.11.2a Parent Route of Administration TermID Version Date / Number	G.k.4.r.11.2b Parent Route of Administration TermID
G.k.7.r Indication for Use in Case		
G.k.7.r.1 Indication as Reported by the Primary Source		
G.k.7.r.2a Indication in MedDRA Terminology (version)	G.k.7.r.2b Indication (MedDRA code)	
H. NARRATIVE CASE SUMMARY AND FURTHER INFORMATION		
H.1 Case Narrative uso de cilostazol en paciente de 10 años con insuficiencia venosa crónica		
H.2 Reporter's comments		
H.4 Sender's comments		