GRIFOLS

CONFIDENTIAL
SUSPECTED ADVERSE REACTION REPORT

PATIENT INFORMATION

Patient initials: _____ **Patient's medical record number:** _____ **Date of Birth:** _____ **Age:** _____

Sex: ☐ Female ☐ Male **Weight (kg):** _____ **If female, is the patient pregnant?** ☐ No (the patient is not pregnant) ☐ Yes (the patient is pregnant)

Allergies: _____

Medical history (medical conditions): _____

_____

SUSPECTED MEDICINE

Name & strength of the medicine: _____

Batch number(s): _____

Dosage & frequency prescribed: _____

Amount received when the reaction occurred: _____

Administration date: _____

Infusion start & stop times: _____

Route of administration & infusion rate: _____

Reason for use (indication): _____

Has the patient previously received this medicine? ☐ No, first time ☐ Yes If yes, please describe previous response: _____

Has the patient previously had <u>any IVIG</u> medication? ☐ No ☐ Yes If yes, please describe previous response: _____

INFORMATION ABOUT THE REACTION

Date of onset of the reaction: _____/_____/_____

Where did the patient receive the infusion? ☐ Outpatient services ☐ Hospital (inpatient) ☐ Other (specify): _____

Description of the reaction: _____

_____

_____

_____

_____

_____

Action taken: ☐ Infusion discontinued ☐ Infusion interrupted ☐ Infusion rate reduced ☐ None ☐ Unknown

Did the adverse event(s) improve following discontinuation? _____

If the infusion was reintroduced, did the reaction(s) reappear after reintroduction? _____

Outcome:
- ☐ Recovered (date of recovery: ___/___/___)
- ☐ Recovered with sequelae (specify sequelae: _____)
- ☐ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Unknown

Severity of the reaction:
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Unknown

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Please indicate the seriousness of the reaction(s) based on the following criteria (tick any/all that apply):

☐ Involved hospitalisation of longer than 24 hours in duration (admission date: ____/____/____ discharge date: ____/____/____)

☐ Lengthened an existing hospitalisation (the patient was already an inpatient prior to receiving the infusion and the patient's stay in hospital was lengthened because of the reaction)

☐ Considered medically significant (seriously jeopardised the patient)

☐ Resulted in persistent or significant disability or incapacity

☐ Was associated with a congenital anomaly or birth defect

☐ Was life threatening

☐ Resulted in death (date of death: ____/____/____ cause of death: _____)

☐ None of the above

Causality (likelihood the suspected medicine caused the events):

☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Not related ☐ Not assessable

TREATMENT OF THE REACTION

Medicine:	Dose:	Date begun:	Date stopped:	Reason for use:

Any other treatment: _____

CONCOMITANT MEDICATIONS

Medicine:	Dose:	Reason for use:

REPORTER INFORMATION

Occupation: ☐ Doctor ☐ Nurse ☐ Other (please specify) _____

Full Name: _____

Email: _____

Location (address): _____

Phone number: _____

Signature: _____ **Date:** _____/_____/_____

Please email this completed report to:
australia_medinfo@grifols.com

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