# Post Market Follow-up Form

FORM-100836 v6.0 Effective Date: 17-Dec-2018

| AMGEN® AUSTRALIA | Fax number: 02 8031 8233<br>Email Address: australiansafety@amgen.com | AER No. |
|---|---|---|

## 1. Reporter Information

☐ Physician
☐ Nurse
☐ Pharmacist
☐ Consumer
☐ _____

| First name: | Last name: | |
|---|---|---|
| Address: | | Zip/Post code: |
| City: | State: | Country: |
| Phone: | Fax or email: | |

## 2. Prescribing Physician (if different than reporter)

| First name: | | Last name: |
|---|---|---|
| Phone: | Zip/Post code: | Country: |

## 3. Patient

| Initial or First Name: | | Initial or Last Name: | | Country: | |
|---|---|---|---|---|---|

| Date of Birth*: (dd-MMM-yyyy) | Age*: ☐ years ☐ months | Age group*: ☐ Infant ☐ Child ☐ Adolescent ☐ Adult ☐ Elderly | Weight ☐ kg ☐ lbs | Height ☐ cm ☐ in | Race/Ethnicity | Gender ☐ Male ☐ Female |
|---|---|---|---|---|---|---|
| | | | | | | |

*Please provide at least one value (i.e. DOB or Age or Age group)

## 4. Suspect Products Information (include dosing details)

| Suspect Product(s) | Product Form | Start Date | Stop Date | Action Taken | Dose/Units/ Frequency | Route | Indication | Lot/Batch/ Serial #: |
|---|---|---|---|---|---|---|---|---|
| Please list all the suspect product(s) below | **01** – Sure Click<br>**02** – Prefilled syringe<br>**03** – Tablet<br>**04** – On Body Injector/Infuser (OBI)<br>**05** - Other | (dd-MON-yyyy) | (dd-MON-yyyy) | **01** – Still being administered<br>**02** – Permanently discontinued<br>**03** - Withheld | | | | (Provide Lot #/ Serial # in the cells below) |
| **Product 1** | | | | | | | | ☐ *Tick if unavailable or unknown* |
| | | | | | | | | |
| **Product 2** | | | | | | | | ☐ *Tick if unavailable or unknown* |
| | | | | | | | | |

## 5. Adverse Event Information:

| Event Term/Symptom | Onset Date (dd-MON-yyyy) | Resolved Date (dd-MON-yyyy) *(If patient died, list date of death)* | Seriousness criteria: 01=Death; 02=Immediately life threatening; 03=Required/prolonged hospitalization; 04=Persistent or significant disability/incapacity; 05=Congenital anomaly /birth defect; 06=Other medically important serious event; 07=None of the above/Non-serious | If Hospitalization / Prolongation: Date Admitted (dd-MON-yyyy) | If Hospitalization / Prolongation: Date Discharged (dd-MON-yyyy) | Causality with product recorded in Section 4 (Y = Yes, N = No): Prod 1 | | Prod 2 | | Outcome: **01** – Resolved; **02** – Not resolved; **03** – Fatal*; **04** – Unknown. *Please provide cause of death, if known in section 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Seriousness Criteria code | | | | | | | |
| | | | | | | Y | N | Y | N | |
| | | | | | | Y | N | Y | N | |
| | | | | | | Y | N | Y | N | |

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## 6. Relevant Concomitant Medications:

| Drug Name (provide brand name if known) | Dosage | | Indication | Start Date (dd-MON-yyyy) | Stop Date (dd-MON-yyyy) | Suspect | |
|---|---|---|---|---|---|---|---|
| | Units | Frequency | | | | Yes | No |
| | | | | | | ☐ | ☐ |
| | | | | | | ☐ | ☐ |
| | | | | | | ☐ | ☐ |

## 7. Relevant Medical History and Allergies*:

*Please also include alcohol/drug/tobacco use/abuse if relevant

| | Onset Date (dd-MON-yyyy) |
|---|---|
| | |
| | |
| | |

**Is the patient/patient's partner pregnant?** ☐ Yes ☐ No ☐ Unk ☐ N/A

**Is the patient/patient's partner breastfeeding?** ☐ Yes ☐ No ☐ Unk ☐ N/A

## 8. Relevant Diagnostic Tests Performed?

☐ **Yes** ☐ **No**, If yes, please attach results or complete the table below:

**Please indicate test unit where applicable (use additional pages if needed)**

| Date | Test Name | Pre-treatment value | AE onset value | AE resolution value | Normal low | Normal high |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

## 9. Event(s) Description: Chronological summary of reported events from section 5

(Please include information on the suspect drug(s) including method of administration and event(s) including the diagnosis, treatment, outcome and re-challenge info, if the event is persistent.)

| Reporter Signature | | Date (dd-MON-yyyy) | |
|---|---|---|---|
| | | | |