

**2**:

(AUS & NZ) +61 2 9035 8670 (AU) 1800 564 594 (NZ) + 61 1800 564 594

Fax:

⊠:

medicalanz@abbvie.com

| COMPASSIONATE ACCESS APPLICATION FORM   |                                |               |       |
|---|--------------------------------|---------------|-------|
| Please complete this form in full and retu  | ırn to medicalanz@abl          | ovie.com      |       |
| Has an application for this patient been submitted before?  | Yes                            | No            | 0     |
| Date drug required  |                                |               |       |
| "PATIENT" INFORMATION   |                                |               |       |
| Patient initials (do not provide full name)   |                                | Date of birth |       |
| ATRAS Code (if applicable)  |                                | Weight (Kg)   |       |
| PRODUCT details   |                                |               |       |
| Name of the Product   |                                |               |       |
| Strength <u>and</u> Direction for use   |                                |               |       |
| Indication or "Condition"<br>and<br><u>Reason for Request</u>   |                                |               |       |
| Is the patient currently being treated with the Product?  | Yes                            | No            |       |
| If YES – is the treatment through PBS?  | Yes                            | No            |       |
| Please note: requests for unapproved products/ indications (not off-label dosing) in Australia will also require TGA Notification/ Approval via their Special Access Scheme. Please follow the links below for further information. |                                |               |       |
| Form  | Pens                           | Syringes      | Other |
| Requested duration of Therapy   |                                |               |       |
| PROPOSED PRODUCT TREATMENT REGIMEN (including concomitant medications used to treat the condition)  |                                |               |       |
|   |                                |               |       |
| PHARMACY DELIVERY DETAILS (for shipment of Product)   |                                |               |       |
| Pharmacy Name & Address (no PO box)   |                                |               |       |
| ₱ PH:   |                                |               |       |
| M Pharmacy email address:   |                                |               |       |
| Prescribing HEALTHCARE PROFESSIONAL DETAILS   |                                |               |       |
| Name:   | AHPRA/MCNZ<br>Registration No. |               |       |
| Address<br>(no PO box):   |                                |               |       |
| <b>☎</b> PH:  |                                | Fax:          |       |
| ☑ Email address:  |                                | Date:         |       |



You as the prescribing HCP are responsible for determining the clinical needs of the Patient & monitoring the outcome of treatment with the Product. You are also responsible for ensuring that the Patient has given the appropriate informed consent prior to commencing treatment with the Product. Any use of the Product outside of its approved indications remains your clinical decision & responsibility.

#### **Adverse Events**

If you become aware of any adverse event &/ or pregnancy relating to the use of any AbbVie product, we request that you report the event directly to AbbVie Pharmacovigilance:

Email: drugsafetyanz@abbvie.com

Fax: +61 2 6100 9780

In addition, as the sponsor of the Products, AbbVie is responsible for monitoring & providing reports regarding the safety profile of the Products. It may therefore be necessary for AbbVie Pharmacovigilance to contact you in response to information submitted as part of this application.

# SAS Special Access Scheme (TGA Australia Only)

Requests for unapproved products/ indications (not off-label dosing) in Australia will also require TGA Notification/ Approval via their Special Access Scheme. Please follow the links below for further information.

Forms: Special access scheme | Therapeutic Goods Administration (TGA)

**Guidelines:** Access to unapproved therapeutic goods - Special Access Scheme | Therapeutic Goods Administration (TGA)

#### Use of personal information

In completing this form, you consent to AbbVie collecting & using the personal information you provide regarding yourself & the Patients ("Personal Information") to contact you in relation to this application & otherwise as necessary to action your application. You also consent to AbbVie contacting you by phone, email or otherwise on an ongoing basis as part of the delivery of AbbVie's medical products & services. If you do not provide the information requested in this form, we may not be able to process your application.

#### **Personal information of the Patient**

You acknowledge that you are authorised, & have provided all necessary notifications to, or obtained consents from, the Patient (or his/ her guardians) to permit you to collect Personal Information you provide to AbbVie regarding the Patient & to disclose that Personal Information to AbbVie for use in accordance with this application.

# **Disclosures**

We may disclose the Personal Information you provide regarding yourself & the Patient to other AbbVie affiliates for the purposes of processing this application, including to recipients outside of Australia & New Zealand located in Singapore & the United States. Further, Personal Information may be disclosed to a third party such as a health authority if AbbVie is required to do so by applicable law, court order or government regulation (e.g. the Therapeutic Goods Act). We will take all reasonable steps to ensure that any third party recipients of the Personal Information protect it in accordance with applicable privacy laws.

### AbbVie's privacy policy

Personal Information will be handled in accordance with AbbVie's privacy policy which details how individuals can access, correct or complain about the handling of their Personal Information, & how Abbvie will respond to those requests of complaints. A copy of AbbVie's privacy policy can be obtained from www.abbvie.com.au/privacy/home.html

## Consent

I the Prescribing HCP (detailed above), hereby acknowledge the terms as set out above and consent to AbbVie Pty Ltd collecting & processing Personal Information for the purposes outlined in this application.

Yes

OFFICE USE ONLY v5 COMP-