Eisai

hhc
human health care

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

The data provided by you shall be used by the company or its affiliates or service provider to evaluate the safety of our product and may be shared with relevant regulatory bodies. You may withdraw your consent anytime, if you wish to

☐ I agree and authorized the company or its affiliates or service provider to use the data provided by me to evaluate the safety of their product. I understand that I can withdraw my consent anytime, if I wish to.

1.Patient Details

Patient Initials/ ☐☐	Gender Male ☐ Female ☐ Other ☐	Age (Year or Month)/

2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms)

b. Medicines Advised by ☐ Pharmacist ☐ Friends/Relatives ☐
Self (Past disease experienced/No past disease experienced) ☐

3. Details of Person Reporting the Side Effect

Name (Optional)

Address

Country:

Telephone No :	Email :

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form: Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐

If Others (Please Specify.....)

5. About the Side Effect

When did the side effect start? dd/mm/yy Side Effect is still Continuing (Yes/No)/

When did the side effect stop? dd/mm/yy dd/mm/yy

6.How bad was the Side Effect? (Please √ the boxes that Apply)

☐ Did not affect daily activities	☐ Affect daily activities
☐ Admitted to hospital	☐ Death
☐ Others	

7.Describe the Side Effect (What did you do to manage the side effect?)

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. You are requested to cooperate with the company officials when they contact you for more details. Please do report even if you do not have all the information.

Please turn the page to read the instructions

Send your report by mail to	
Eisai Pharmaceuticals Africa (Pty) Ltd. 2nd Floor, Golden Oak House, Ballyoaks Office Park, 35 Ballyclare Drive, Bryanston, Johannesburg – 2191, Gauteng, South Africa **Email: EPA-vigilance@eisai.co.za** For more details visit us at **http://www.eisai.co.za**	 Call us on **+27-10-590-4325** **Monday to Friday** **Between (9 AM to 4 PM)**

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Company staff is not expected to and will not disclose the reporter's identity in response to a request from the public.

Instructions to Complete the Reporting Form

Section 1 - Patient Details

- ✓ In patient Initial, write first letter of the name and first letter of the surname (e.g. Sumit Kumar-SK).
- ✓ Provide personal information (Gender, Age).

Section -2 Health Information

- ✓ Provide reason(s) for taking medicines and medicines advised by (Doctor, Pharmacists, Friends/ Relatives and Self).

Section 3 - Details of Person Reporting the Side Effect

- ✓ Provide the name (optional), address; telephone no. and email are necessary to assess the report.

Section 4 - Details of the Medicines Taking/Taken

- ✓ Give all details about the Medicines (Name of Medicines, Quantity of Medicines taken, Expiry Date, start and stop date of Medicines) that have caused side effect.
- ✓ Please provide Dosage form (Tablets, Capsule, injections, Oral liquid) and if others please specify.

Section 5 - About the Side Effect

- ✓ Provide side effect start and stop dates and also specify whether the side effect is still continuing.

Section 6 - How bad was the Side Effect

- ✓ Please tick marks the appropriate boxes that apply.

Section 7- Describe the Side Effect

- ✓ Please describe the details of sideefect and what treat ment was taken to manage the side effect.

Thank you for taking time to complete this form