Adverse Event Reporting Form

1. Reporter Information

Name:

Role (e.g., Healthcare Professional, Patient, Caregiver):

Phone Number:

Email Address:

Preferred Method of Contact: [ ] Email [ ] Phone

2. Patient Information (If available)

Initials (or Code):

Age:

Sex: [ ] Male [ ] Female [ ] Other

Weight (kg):

Height (cm):

3. Product Information

Product Name:

Batch/Lot Number (if known):

Dosage Form (e.g., tablet, injection):

Dosage (e.g., 500 mg twice daily):

Indication (Reason for use):

Start Date of Use: ____ / ____ / _____

Stop Date of Use (if applicable): ____ / ____ / _____

4. Adverse Event Details

Description of the Adverse Event:

Date of Event Onset: ____ / ____ / _____

Seriousness of Event: (tick all that apply)

[ ] Death [ ] Life-threatening [ ] Hospitalization

[ ] Disability [ ] Birth Defect [ ] Other

Outcome: [ ] Recovered [ ] Recovering [ ] Not Recovered [ ] Fatal

[ ] Unknown

5. Concomitant Medications

(Other medicines taken at the same time):

6. Additional Information

(e.g., relevant medical history, allergies):

7. Consent

[ ] I confirm that the information provided is accurate.

[ ] I agree to the use of the data for pharmacovigilance activities.

Signature (if printed): _____

Date: ____ / ____ / _____

Thank you for helping us ensure the safety of our products.

ARES Scientific Bureau - Pharmacovigilance Department

Email: Pharmacovigilance@ares-pharma.co