1. Suspect Drug Details

Suspected Drug: Indications: Start date (DD/MMM/YY): ____/____/

Total daily dose/route: Batch number: Stop date (DD/MMM/YY):____/____/

2. Second Suspect Drug Details (if relevant)

Suspected Drug: Indication: Start date (DD/MMM/YY): ____/____/

Total daily dose/route: Batch number: Stop date (DD/MMM/YY): ____/____/

3. Reporter

Name: Profession:

Institution/ Hospital: Address:

Tel: Fax: Email:

4. Patient Information

Patient Initials: _____ Gender F ☐ M ☐ Date of Birth (DD/MMM/YY) ____/____/

Age:

Height_____cm Weight:_____kg ☐ Pregnancy: No ☐ Yes ☐

If yes, pregnancy week: _____

5. Description of adverse drug reaction(s) Continue separate sheet if more than 2 reactions	
1.)	Date of onset (DD/MMM/YY) ____/____/ Resolution date (DD/MMM/YY) ____/____/ Causality: ☐ Related ☐Unrelated ☐Unknown Did the reaction reappear after reintroduction of drug? ☐ Yes ☐ No ☐ Unknown ☐ Not applicable
2.)	Date of onset (DD/MMM/YY) ____/____/ Resolution date (DD/MMM/YY) ____/____/ Causality :☐ Related ☐ Unrelated ☐ Unknown Did the reaction reappear after reintroduction of drug? ☐ Yes, ☐No ☐Unknown ☐ Not applicable

6. Action Taken with suspect drug

☐ Product discontinued due to AE ☐ Dose Increased ☐ None
☐ Dose Decreased ☐ Other (please specify):

7. Outcome of ADR: (Tick all applicable)

☐ Recovered without sequelae* Date ____/____/
☐ Recovered with sequelae Date ____/____/
☐ Ongoing
☐ Improved, but not yet recovered Date ____/____/
☐ Death Date ____/____ Autopsy ☐ Yes ☐ No
☐ Unknown

*Sequelae: a morbid condition following or occurring as a consequence of another condition or event

8. Seriousness: Was the event serious or non-serious? (please indicate below)

The patient □ Recovered, date: □ Recovering □No improvement □ Fatal □Unknown
Event subsided after stopping (dechallenge) □No □ Yes □ Unknown
Event reappear after reintroducing (rechallenge) □No □ Yes □ Not applicable Specific antagonist or treatment used: □No □Yes, specify:……..

9. Relevant Medical History Concomitant disease(s), pregnancy (Diabetes, Hypertension…. etc.)

1-
2-
3-
4-
5-

10. Relevant Concomitant drug(s)	Dose	Frequency	Rout
1- 2- 3- 4- 5-			

Dear healthcare professional: We realize that filling this form requires time to complete, but reporting adverse drug reactions is indispensable for safe use of medication. The SFDA can judge the safety of medicinal products in Saudi Arabia only if sufficient information is provided.

- Confidentiality: Reporter's and patient's identity are held in strict confidence by Al Razi Pharmaceutical industry and fully protected of the law, information provided by the reporter will be strictly protected and will not be used in any way against him / her.
- Adverse Drug Reaction (ADR) is a response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction, or modification of physiological function.
- A serious adverse event or reaction is any untoward medical occurrence that at any dose:
  - Results in death.
  - Requires hospitalization or prolongation of existing hospitalization.
  - Results in persistent or significant disability/incapacity.
  - Life-threatening.

After filling the report, please send it to PV@alrazi-pharma.com .