|  |
| --- |
| **A.Source of AE/ Special Situation** |
| □ Written complaints □ telephonic □ voice message □ oral □ email messages□ others (specify) |
| **B. Report Type (select more than one if necessary** |
| □ Any spontaneous reports of ADR / AE.□ Any suspected transmission via a medicinal product □ ADR/AE related to technical complaints□ ADR/AE related to medical information queries□ ADR/AE from named patient use □ ADR/AE from non-interventional studies□ Pregnancy or lactation exposure□ Medication abuse□ Medication misuse | □ Medication overdose□ Medication errors□ Off-label use□ Occupational exposure□ Drug interaction□ Falsified Medicinal Product□ Unexpected therapeutic □ Lack of efficacy□ If Other please specify. |
| **C. Patient information** |
| Patient Initials: | Sex: □ M □ F | Date of Birth | Age /Age Group | Weight  | Height | Nationality |
|  | If pregnant,which month |  |  |  |  |  |
| Medical History/Known allergies |
| **D. Suspected Pharmaceutical Products /Device/Other category**  |
| Trade Name, Dosage Form& Strength | Batch No /Lot No. | Exp.Date | Route  | Generic Name |
|  |  |  |  |  |
| Manufacturer | Dose per Day | Date Started | Date Stopped | Prescribed for |
|  |  |  |  |  |
| **Concomitant Medications / Other drugs taken during the last 3 months** |
| Trade Name, Dosage Form& Strength | Date Started | Date Stopped | Prescribed for |
|  |  |  |  |
| **E. Suspected Adverse Reactions/Drug Problem**  |
| Describe the Reaction/Problems(Please list the most significant adverse reactions first – (If necessary use additional blank page) |
| Date of onset\_\_\_\_\_or Reaction appeared after \_\_\_\_\_\_ days of treatmentDate reaction stopped\_\_\_\_\_\_\_\_Did a similar reaction occur in this patient earlier □ Yes □ NoRelated to similar drugs□ Yes □ NoIf Yes please specify If treatment given please specify | **Outcome**□ Recovered /resolved on **\_\_\_/\_\_\_\_\_/\_\_\_\_\_**□ Recovering/resolving□ Not Recovered/not resolved (further information has to be provided as soon as possible□ Resolved with sequelea□ Fatal□ Unknown |
| **Seriousness: Do you consider the reaction as serious?** □ Yes □ No If yes, please indicate why? □ Death (due to the reaction) □ Life Threatening □ Persistent disability□ Hospitalization \_\_\_ initial or prolonged□ Congenital anomaly/birth defect □ Other medically important condition, please specify |
| **F. Reporter Information** |
| Name\_\_\_\_\_\_\_\_\_\_\_ Profession\_\_\_\_\_Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Report \_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_ | Has this case been already reported to national health authority or any other organization?If yes, to whom? \_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_ |
| Thank you for sending back this Safety FormEmail : infopv@ispoman.comPhone : 00968 24822132 / 24822134Fax : 00968 24871342 |