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|  | | | | | | | **BLAU FARMACÊUTICA** | | | | | | | | | | | **Annex I SOP CO FVG 004/3** | | | | | | | | | |
| **ADVERSE DRUG EVENT REPORT (RAMED)** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name of Notifier:**  **{Health professional)** | | | | | | | | | | | | | | | **Professional category:** | | | | | | | | | | | | |
| **Enrollment number:** | | | | | | | | | | | | **State:** |
| **TEL .: DDD ( )** | | | | | | | | | | | | | **Email:** | | | | | | | | | | | | | | |
| **Address:** | | | | | | | | | | | | | | | **Zip Code:** | | | | | | | | | | | | |
| **Company:** | | | | | | | | | | | | | | | **CNPJ:** | | | | | | | | | | | | |
| **PATIENT DATA** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Patient's initials;** | | | **Age** | | | | | **Date of birth** | | | | | **Sex** | | **Pregnancy** | | | | | **Height** | | | | | | **Weight** | |
|  | | |  | | | | | **\_\_\_/\_\_ /\_\_\_** | | | | |  | |  | | | | |  | | | | | |  | |
| **Main Diagnosis:** | | | | | | | | | | | | | | | **Inpatient care:** | | | | | **񱹚 yes** | | | | **񱹚 no** | | | |
| **Concomitant Diseases and Addictions:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Allergy or other previous drug reactions:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SUSPECTED DRUG** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Drug:** | | | | | | **Presentation:** | | | | | | | **Batch:** | |  | | **Manufacturing Date:** | | | | | | | **Expiration Date:** | | | |
| **Dosage and Administration:** | | | | | | **Route of Administration:** | | | | | | | **Reason for indication:** | |  | | **Start of use:**  ***\_\_\_/\_\_\_\_/\_\_\_*** | | | | | | | **End of use:**  ***\_\_\_/\_\_\_\_/\_\_\_*** | | | |
| **Discontinued drug:** | | | | | | **񱹚 yes** | | | | **񱹚 no** | | | **If so, On what date?**  **\_\_\_\_\_/\_\_\_\_\_\_ /\_\_\_\_\_\_\_** | | | | | | | | | | | | | | |
| **CONCOMITANT DRUGS** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Drug:** | | | | | | **Dosage and Administration:** | | | | **Route of Administration:** | | | **Start of use:** | | **End of use:** | | **Reason for indication:** | | | | | | | | **Batch:** | | |
| **1.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **2.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **3.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **4.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **5.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **6.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **7.** | | | | | |  | | | |  | | |  | |  | |  | | | | | | | |  | | |
| **ADVERSE EVENT REPORT** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Reaction:** | | | | | | | | | | | | | **Reaction start date:** | | | | | | | | | **End date of the reaction:** | | | | | |
| **Reaction:** | | | | | | | | | | | | | **Reaction start date:** | | | | | | | | | **End date of the reaction:** | | | | | |
| **Reaction:** | | | | | | | | | | | | | **Reaction start date:** | | | | | | | | | **End date of the reaction:** | | | | | |
| **1** | **Did the reaction cause death?** | | | | | | | | | | | | **񱹚 yes** | | **񱹚 no** | | | | **Causa Mortis:** | | | | | | | | |
| **2** | **Did the reaction cause hospitalization?** | | | | | | | | | | | | **񱹚 yes** | | **񱹚 no** | | | | **񱹚 Not applicable or 4 unknown** | | | | | | | | |
| **3** | **Did the reaction prolong hospitalization?** | | | | | | | | | | | | **񱹚 yes** | | **񱹚 no** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| **4** | **Has the reaction involved a risk of death?** | | | | | | | | | | | | **񱹚 YES** | | **񱹚 NO** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| **5** | **Is the reaction gone or did it improve after drug withdrawal?** | | | | | | | | | | | | **񱹚 yes** | | **񱹚 no** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| **6** | **Did the reaction subside or improve with dose adjustment?** | | | | | | | | | | | | **񱹚 YES** | | **񱹚 NO** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| **7** | **Did the reaction reappear after the drug was withdrawn?** | | | | | | | | | | | | **񱹚 YES** | | **񱹚 NO** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| **8** | **Does the patient have a similar history with the same or similar drug?** | | | | | | | | | | | | **񱹚 YES** | | **񱹚 NO** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| **9** | **Has the reaction been confirmed by any objective evidence?** | | | | | | | | | | | | **񱹚 YES** | | **񱹚 NO** | | | | **񱹚 Does not apply or is unknown** | | | | | | | | |
| 10 | Corrective measures - Treatment administered for the control of ADR or any other related procedure. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11 | Clinical report of the case and reactions, with relevant laboratory data - Record any and all clinical information regarding the patient that is deemed important. UTILIZE THIS FIELD TO DESCRIBE ANY RELEVANT FACT THAT  IS CONSIDERED IMPORTANT OR CLARIFIES SOME INFORMATION REGISTERED IN ANY OTHER FIELD. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Evolution: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12 | 񱹚 Recovered | | | 񱹚 In recovery | | | | | 񱹚 Recovered with sequelae | | | | | 񱹚 Not Recovered | | | | | | | 񱹚 Unknown outcome | | | | | | |
| 13 | Relationship of the Drug with the Reaction | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 񱹚 - Unlikely | | | | 񱹚 Possible | | | | | | 񱹚 Likely | | | | | 񱹚 Impossible to classify | | | | | | | 񱹚 Not Evaluated by Physician | | | | |
| Who was informed? | | 񱹚 Health Authority | | | | | | | | | 񱹚 - Manufacturer | | | | | Others: | | | | | | | | | | | |
| Date of reporting: | | | | | | | | | | | | Stamp / Signature | | | | | | | | | | | | | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_\_ | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Attach additional page if necessary. | | | | | | | | | | | | | | | | | | | | | | | | | | | |