**Safety Alert Form**

Please pay attention to the recommendations above each section when filling out the form. Provide as much information as possible for each section.

Please note that the fields marked by (\*) are mandatory.

**Please ensure that you have provided the minimum required information:**

* **Patient or consumer of the product** (initials / gender / age);

NB: personal data of the patient or consumer of the product is not to be specified.

* **Suspected product** (even if the casual relationship is doubtful);
* **Description of the adverse drug reaction or other safety information** (date of the incident, word-for-word description of the events);
* **Original source** (the person that provided the information and his/her contact details);

You can provide the name or initials, address or qualifications (e.g., doctor, pharmacist, etc.); contact details are required for feedback (phone number, postal address, E-mail).

* **Date** on which you received the information.

**How should we address you?** \*

|  |
| --- |
| Insert text |

**Contact details** that you are willing to provide \*

**Your phone number:**

|  |
| --- |
| Insert text |

**Your E-mail:**

|  |
| --- |
| Insert text |

**Your place of employment (for healthcare professionals):**

|  |
| --- |
| Insert text |

**Your position (for healthcare professionals):**

|  |
| --- |
| Insert text |

**INFORMATION ON THE PATIENT OR CONSUMER OF THE PRODUCT**

**Initials of the patient:**

|  |
| --- |
| Insert text |

**Gender:**\*

Male Female

**Age** (please specify if possible):

|  |
| --- |
| Insert text |

**Known allergic reactions:**

|  |
| --- |
| Insert text |

**Chronic diseases:**

|  |
| --- |
| Insert text |

**Form of treatment:**

Out-patient In-patient Self-treatment

**Describe concomitant treatment** (any drugs or non-drug therapy methods):

|  |
| --- |
| Insert text |

**INFORMATION ON THE SUSPECTED PRODUCT**

**Name of the product:**\*

|  |
| --- |
| Insert text |

**Form** (tablets, capsules, solution, etc.):

|  |
| --- |
| Insert text |

**Batch No:**

|  |
| --- |
| Insert text |

**Manufacturer:**

|  |
| --- |
| Insert text |

**Dosage:**

|  |
| --- |
| Insert text |

**Administration** (oral, intramuscular, intravenous, etc.):

|  |
| --- |
| Insert text |

**Indications for use of the product:**

|  |
| --- |
| Insert text |

**Starting date of use:**

|  |
| --- |
| Insert text |

**Final date of use:**

|  |
| --- |
| Insert text |

**DESCRIPTION OF THE ADVERSE DRUG REACTION OR OTHER SAFETY INFORMATION**

**Description of the adverse drug reaction or other safety information** (please specify the date of the incident and provide as much detail as possible on the events that transpired):\*

|  |
| --- |
| Insert text |

**Date on which you received/learned the information** \*

|  |
| --- |
| Insert text |

**Consent to processing of information**

Please note that in accordance with Federal Law No 152-FZ dd July 27, 2007 on Personal Data provision of personal data or any other confidential information by you is not mandatory.

You hereby confirm your legal capacity and voluntarily give NovaMedica LLC your consent to processing of your personal data or any other confidential information that you may send us via the website [www.novamedica.com](http://www.novamedica.com) (online), E-mail or mail, or provide by phone for the following purposes:

- contacting you, including for the purpose of answering your question or providing the information you requested;

- clarifying your information or requesting additional information, if necessary;

- monitoring safety of pharmaceutical products, including for the purpose of quality control and/or counterfeit detection;

- complying with other requirements of the applicable laws of the Russian Federation.

You are entitled at any time to receive confirmation of the fact that your personal data is being processed, as well as any other information related to such processing in accordance with the procedure set forth by Federal Law 152-FZ dd July 27, 2007 on Personal Data. You are entitled to review the personal data being processed, as well as receive the information on the purpose of such processing, category of the data being processed, actions performed with respect to such data, recipients of such data and guarantees in case such data is transferred to third parties, time of processing and data sources.

**I hereby confirm that I give my consent to NovaMedica LLC to processing of my personal data and any other information contained in this safety alert message** \*

**Confirmed**\*

Please note that if you refuse to consent to processing of the information, this safety alert message will not be considered or processed.