


## ADVERSE EVENT REPORT FORM

	<b>BIOTON S.A.</b> 05-850 Ożarów Mazowiecki, ul. Poznańska 165 tel.: 022 721 46 00, fax: 022 721 46 01 mobile 0510 024 459 email: <a href="mailto:tarasiuka@bioton.pl">tarasiuka@bioton.pl</a>	<b>CONFIDENTIAL</b>	
REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOW UP			
PATIENT (INITIALS):	PATIENT MEDICAL RECORD NUMBER(S):  PATIENT NUMBER (FOR CLINICAL STUDY):	COUNTRY: <i>(WHERE EVENT OCCURED)</i>	
DATE OF BIRTH: <i>(dd/mm/yyyy)</i>	AGE:	PATIENT AGE GROUP: <input type="checkbox"/> NEONATE <input type="checkbox"/> INFANT <input type="checkbox"/> CHILD <input type="checkbox"/> ADOLSCENT <input type="checkbox"/> ADULT <input type="checkbox"/> ELDERLY	
WEIGHT(kg):	HEIGHT (cm):	SEX: <input type="checkbox"/> M <input type="checkbox"/> F	ETHNIC ORIGIN: <input type="checkbox"/> Caucasian <input type="checkbox"/> Non-Caucasian
IF FEMALE, PREGNANT? <input type="checkbox"/> YES* <input type="checkbox"/> NO		IF YES: _____ WEEKS	LAST MENSTRUAL PERIOD DATE: <i>(dd/mm/yyyy)</i>

*\* if yes, please complete also a pregnancy form.*

ADVERSE EVENT(S) <i>(in order of seriousness)</i>	STARTED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ENDED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ONGOING YES/NO
1.			
TIME INTERVAL BETWEEN BEGINNING OF SUSPECT DRUG ADMINISTRATION AND START OF REACTION:		TIME INTERVAL BETWEEN LAST DOSE AND START OF REACTION:	
SEVERITY OF EVENT/REACTION: <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE			
OUTCOME OF REACTION(S) AT THE TIME OF LAST OBSERVATION: <input type="checkbox"/> RECOVERED/RESOLVED <input type="checkbox"/> RECOVERING/RESOLVING <input type="checkbox"/> NOT RECOVERED/NOT RESOLVED <input type="checkbox"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="checkbox"/> FATAL <input type="checkbox"/> UNKNOWN			

*PLEASE COMPLETE AS ACCURENTLY AS POSSIBLE, DATE, SIGN AND RETURN THIS FORM TO BIOTON AS SOON AS POSSIBLE.  
FAX 022 721 46 01*

ADVERSE EVENT(S) <i>(in order of seriousness)</i>	STARTED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ENDED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ONGOING YES/NO
2.			
TIME INTERVAL BETWEEN BEGINNING OF SUSPECT DRUG ADMINISTRATION AND START OF REACTION:		TIME INTERVAL BETWEEN LAST DOSE AND START OF REACTION:	
SEVERITY OF EVENT/REACTION: <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE			
OUTCOME OF REACTION(S) AT THE TIME OF LAST OBSERVATION: <input type="checkbox"/> RECOVERED/RESOLVED <input type="checkbox"/> RECOVERING/RESOLVING <input type="checkbox"/> NOT RECOVERED/NOT RESOLVED <input type="checkbox"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="checkbox"/> FATAL <input type="checkbox"/> UNKNOWN			
ADVERSE EVENT(S) <i>(in order of seriousness)</i>	STARTED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ENDED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ONGOING YES/NO
3.			
TIME INTERVAL BETWEEN BEGINNING OF SUSPECT DRUG ADMINISTRATION AND START OF REACTION:		TIME INTERVAL BETWEEN LAST DOSE AND START OF REACTION:	
SEVERITY OF EVENT/REACTION: <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE			
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ADVERSE EVENT(S) <i>(in order of seriousness)</i>	STARTED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ENDED: <i>(dd/mm/yyyy) + (hh:mm)</i>	ONGOING YES/NO
4.			
TIME INTERVAL BETWEEN BEGINNING OF SUSPECT DRUG ADMINISTRATION AND START OF REACTION:		TIME INTERVAL BETWEEN LAST DOSE AND START OF REACTION:	
SEVERITY OF EVENT/REACTION: <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE			

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PREVIOUS EXPOSURE TO SUSPECT DRUG?		
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> UNKNOWN
SUSPECT DRUG PREVIOUSLY TOLERATED?		
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> UNKNOWN/NOT APPLICABLE

\*S=SUSPECT    C=CONCOMITANT    I=INTERACTING

ADMINISTERED DRUG	BATCH N <sup>o</sup>	ROLE*	DOSE	UNIT	FREQUENCY	ROUTE	THERAPY DATES (dd/mm/yyyy)+ TIME (hh:mm)		INDICATION FOR USE
							FROM	TO	
2.									

ACTION (S) TAKEN WITH DRUG:

DRUG WITHDRAWN    STOP DATE: \_\_\_\_\_

DOSE REDUCED        NEW DOSE: \_\_\_\_\_

DOSE INCREASED      NEW DOSE: \_\_\_\_\_

DOSE NOT CHANGED

UNKNOWN

NOT APPLICABLE

EFFECT OF DECHALLENGE FOR SUSPECT DRUG(S) ONLY  
(DID EVENT ABATE AFTER STOP DRUG?)

YES                       NO

EFFECT OF RECHALLENGE (OR RE-EXPOSURE) FOR SUSPECT DRUG(S) ONLY:  
(DID REACTION RECUR ON READMINISTRATION?)

YES                       NO

RELATEDNESS OF DRUG TO EVENT: *IN YOUR OPINION THE CAUSAL RELATIONSHIP OF SUSPECT DRUG TO ADVERSE EVENT IS:*

NOT RELATED     UNLIKELY     POSSIBLE     PROBABLE

PREVIOUS EXPOSURE TO SUSPECT DRUG?		
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> UNKNOWN
SUSPECT DRUG PREVIOUSLY TOLERATED?		
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> UNKNOWN/NOT APPLICABLE

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							FROM	TO	
3.									

ACTION (S) TAKEN WITH DRUG:

DRUG WITHDRAWN    STOP DATE: \_\_\_\_\_

DOSE REDUCED        NEW DOSE: \_\_\_\_\_

DOSE INCREASED      NEW DOSE: \_\_\_\_\_

DOSE NOT CHANGED

UNKNOWN

NOT APPLICABLE

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(DID EVENT ABATE AFTER STOP DRUG?)

YES  NO

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EFFECT OF RECHALLENGE (OR RE-EXPOSURE) FOR SUSPECT DRUG(S) ONLY:  
(DID REACTION RECUR ON READMINISTRATION?)

YES  NO

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NOT RELATED  UNLIKELY  POSSIBLE  PROBABLE

---

PREVIOUS EXPOSURE TO SUSPECT DRUG?

YES  NO  UNKNOWN

---

SUSPECT DRUG PREVIOUSLY TOLERATED?

YES  NO  UNKNOWN/NOT APPLICABLE

\*S=SUSPECT C=CONCOMITANT I=INTERACTING

ADMINISTERED DRUG	BATCH N <sup>o</sup>	ROLE*	DOSE	UNIT	FREQUENCY	ROUTE	THERAPY DATES (dd/mm/yyyy)+ TIME (hh:mm)		INDICATION FOR USE
							FROM	TO	
4.									

ACTION (S) TAKEN WITH DRUG:

DRUG WITHDRAWN STOP DATE: \_\_\_\_\_

DOSE REDUCED NEW DOSE: \_\_\_\_\_

DOSE INCREASED NEW DOSE: \_\_\_\_\_

DOSE NOT CHANGED

UNKNOWN

NOT APPLICABLE

EFFECT OF DECHALLENGE FOR SUSPECT DRUG(S) ONLY  
(DID EVENT ABATE AFTER STOP DRUG?)

YES  NO

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EFFECT OF RECHALLENGE (OR RE-EXPOSURE) FOR SUSPECT DRUG(S) ONLY:  
(DID REACTION RECUR ON READMINISTRATION?)

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PREVIOUS EXPOSURE TO SUSPECT DRUG?

YES  NO  UNKNOWN

---

SUSPECT DRUG PREVIOUSLY TOLERATED?

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\*S=SUSPECT C=CONCOMITANT I=INTERACTING

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RELEVANT MEDICALY HISTORY AND CONCURRENT CONDITIONS:

ALCOHOL    SMOKING    DRUG ABUSE    ORAL CONTRACEPTIVES    DIET

RADIATION THERAPY    IMPLANTS    ALLERGIES\*    DISTURBED METABOLISM\*

\*ADDITIONAL INFORMATION: \_\_\_\_\_

MEDICAL HISTORY/ DISEASE /SURGICAL PROCEDURE:	START DATE: (dd/mm/yyyy)	CONTINUING: YES/NO/UNKNOWN	END DATE: (dd/mm/yyyy)	COMMENTS:
1.				
2.				
3.				
4.				

MEDICAL HISTORY PRIOR TO EVENT:

RELEVANT PAST DRUG HISTORY

	DRUG NAME:	DOSE	UNIT	BATCH N°	FREQUENCY	ROUTE	THERAPY DATE (dd/mm/yyyy) TIME (hh:mm)		INDICATION FOR USE	ADVERSE REACTION? YES/NO
							FROM	TO		
1.										
2.										
3.										
4.										

**FOR A PARENT-CHILD/FETUS REPORT, PLEASE COMPLETE THE INFORMATION CONCERNING THE PARENT:**

PARENT AGE: \_\_\_\_\_ DATE OF BIRTH OF PARENT:  
(dd/mm/yyyy)

WEIGHT OF PARENT (kg): \_\_\_\_\_ HEIGHT OF PARENT(cm): \_\_\_\_\_ SEX OF PARENT: \_\_\_\_\_ LAST MENSTRUAL PERIOD DATE: \_\_\_\_\_

RELEVANT MEDICALY HISTORY AND CONCURRENT CONDITIONS:

ALCOHOL    SMOKING    DRUG ABUSE    ORAL CONTRACEPTIVES    DIET

RADIATION THERAPY    IMPLANTS    ALLERGIES    DRUG ABUSE    DISTURBED METABOLISM

ADDITIONAL INFORMATION: \_\_\_\_\_

MEDICAL HISTORY DISEASE /SURGICAL PROCEDURE:	START DATE: (dd/mm/yyyy)	CONTINUING: YES/ON/UNKNOWN	END DATE: (dd/mm/yyyy)	COMMENTS:
1.				
2.				
3.				
4.				

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MEDICALY HISTORY PRIOR TO EVENT:

RELEVANT PAST DRUG HISTORY

DRUG NAME:	DOSE	UNIT	BATCH N <sup>o</sup>	FREQUENCY	ROUTE	THERAPY DATE (dd/mm/yyyy) TIME (hh:mm)		INDICATION FOR USE	ADVERSE REACTION? YES/NO
						FROM	TO		
1.									
2.									
3.									
4.									

IN CLINICAL STUDIES ONLY:

STUDY NAME:

SPONSOR STUDY NUMBER:

EVENT OCCURED IN THE FOLLOWING STUDY PERIOD:

- PRE - TREATMENT  
 DURING TREATMENT  
 POST - TREATMENT

THE BLIND WAS BROKEN:

- YES\*     NO     NA (OPEN LABEL STUDY)

*\* if yes, please specify the date.*

NARRATIVE SUMMARY (please specify whether there is an alternate cause for this event):

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ARE THERE ANY ADDITIONAL DOCUMENTS ATTACHED TO THIS FORM?

NO       YES\* (please specify) .....

REPORTER NAME AND ADDRESS (*IN CONFIDENCE*):

Tel.:  
Fax:  
e-mail:

SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

SOURCE (FOR BIOTON USE):

- CLINICAL STUDY
- SPONTANEOUS REPORT
- LITERATURE REFERENCE: \_\_\_\_\_
- OTHER PLEASE SPECIFY: \_\_\_\_\_

SPONTANEOUS REPORT FROM (FOR BIOTON USE):

- PHYSICIAN
- PHARMACIST
- OTHER HEALTH PROFESSIONAL
- LAWYER
- CONSUMER OR OTHER NON HEALTH PROFESSIONAL

WAS EVENT REPORTED TO NATIONAL AUTHORITY BY YOU?

YES       NO

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