

## **Adverse Drug Reaction Report**

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Initials:	A. Patient											
B. Reporter   Healthcare Professional?   yes   no   If yes, please provide Healthcare Professional details:   Consumer (patient caregiver or other)   Patient Name:   Name:   Address:   Address:   Address:   Address:   Phone number:   E-mail:   E-mail:   Consumer (patient caregiver or other)   Patient Name:   Address:   Phone number:   E-mail:   E-mail:	Initials:	Date of Birtl	h: Age/Age	Group:	Gender	:	Pregna	ncy:	Weight:		Height:	
Healthcare Professional?					—   🗆 f 🗆 r		we			_kg	cm	
Healthcare Professional?		I					1				<u>I</u>	
If yes, please provide Healthcare Professional details:	B. Reporter	•										
Physician   Pharmacist   Others	Healthcare Professional? ☐ yes ☐ no											
Name: Address: Phone number: E-mail:  Consent for Fresenius Kabi to follow-up with consumer/patient for more information?	If yes, please	If no, please provide consumer/patient details:										
Address: Phone number: E-mail:  Consent for Fresenius Kabi to follow-up with consumer/patient for more information?   yes   no   not applicable Consent for Fresenius Kabi to follow-up with Healthcare Professional?   yes   no   not applicable Note: please fill the Healthcare Professional contact details above accordingly.  C. Drug(s) (Trade name or active substance / dosage form)  1	☐ Physician	$\square$ Consumer (patient caregiver or other) $\square$ Patient										
Phone number: E-mail:  Consent for Fresenius Kabi to follow-up with consumer/patient for more information?	Name:						Name:					
E-mail:  Consent for Fresenius Kabi to follow-up with consumer/patient for more information?    yes    no    not applicable Consent for Fresenius Kabi to follow-up with Healthcare Professional?    yes    no    not applicable Note: please fill the Healthcare Professional contact details above accordingly.  C. Drug(s) (Trade name or active substance / dosage form)  1	Address:						Address:					
Consent for Fresenius Kabi to follow-up with consumer/patient for more information?   yes   no   not applicable   Consent for Fresenius Kabi to follow-up with Healthcare Professional?   yes   no   not applicable   Note: please fill the Healthcare Professional contact details above accordingly.  C. Drug(s) (Trade name or active substance / dosage form)  1	Phone numb	er:				Phone number:						
Consent for Fresenius Kabi to follow-up with Healthcare Professional?	E-mail:					E-mail:						
Note: please fill the Healthcare Professional contact details above accordingly.    C. Drug(s) (Trade name or active substance / dosage form)	Consent for Fresenius Kabi to follow-up with consumer/patient for more information? $\square$ yes $\square$ no $\square$ not applicable								☐ not applicable			
C. Drug(s) (Trade name or active substance / dosage form)  1 2 3 4 5 Suspected causality with drug No.									o 🗆 not a	applica	able	
Administration   (dose and frequency)   start   end	Note: please fill the Healthcare Professional contact details above accordingly.											
form)  1 2 3 4 5 Suspected causality with drug No.	name or active				on (c	dose and	treatr	treatment		cation		
2 3 4 5 Suspected causality with drug No.	form)							Start	Cild			
3 4 5 Suspected causality with drug No.												
4												
Suspected causality with drug No.												
Suspected causality with drug No.												
*If Batch/Lot no. of Fresenius Kabi suspect drugs is unavailable, please fill with appropriate reason(s): "asked but unknown", "unavailable & consent not received for follow-up" or "unavailable & follow-up requested".  D. Adverse Reaction(s) [please describe the reaction(s) and any treatment given]:  Start date: Stop date: Duration:  Seriousness Criteria of Reaction(s)  Death (autopsy:   yes   no)			Na 🗆 1 🗆	2 🗆		N +:	:-!		_			
Start date: Stop date: Duration:  Seriousness Criteria of Reaction(s)  Death (autopsy:   yes   no)   life threatening   complete recovery   recovered with sequelae hospitalization   not yet recovered   not yet recovered   recovering   not data     permanent injury or disability   recovering   Reappearance after re-challenge	*If Batch/Lot no. of Fresenius Kabi suspect drugs is unavailable, please fill with appropriate reason(s): "asked but unknown"											
Seriousness Criteria of Reaction(s)  Death (autopsy:  yes  no) Ifie threatening  not yet recovered hospitalization permanent injury or disability important medical event  Death (autopsy:  yes  no) Unknown  yet recovery recovered with sequelae recovery not yet recovered recovered yes  no  no data  Improvement after discontinuation yes  no  no data  Improvement after discontinuation yes  no  no data  Reappearance after re-challenge	<b>D. Adverse Reaction(s)</b> [please describe the reaction(s) and any treatment given]:											
□ Death (autopsy: □ yes □ no)       □ unknown       □ yes □ no □ no data         □ hospitalization or prolonged hospitalization       □ recovered with sequelae not yet recovered       □ not yet recovered       □ recovering         □ important medical event       □ recovering       Reappearance after re-challenge	Start date: Stop date: Duration:											
☐ life threatening ☐ complete recovery ☐ yes ☐ no ☐ no data ☐ hospitalization or prolonged hospitalization ☐ not yet recovered ☐ permanent injury or disability ☐ important medical event ☐ Reappearance after re-challenge					_							
<ul> <li>☐ hospitalization or prolonged hospitalization</li> <li>☐ permanent injury or disability</li> <li>☐ important medical event</li> <li>☐ complete recovery</li> <li>☐ recovered with sequelae</li> <li>☐ not yet recovered</li> <li>☐ recovering</li> <li>☐ Reappearance after re-challenge</li> </ul>								□ ves □ no □ no data				
hospitalization	_			·								
☐ important medical event Reappearance after re-challenge	hospitalization			$\square$ not yet recovered								

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In cases of serious Adverse Reactions, it may be helpful to **attach doctor and/or hospital discharge letter**.

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## **Adverse Drug Reaction Report**

smoking, alcohol, liver-/renal deterioration):	cs (e.g. underlying and concomitant diseases, other drugs, allergies,						
F. Relevant Investigations and Laboratory Data (with date and normal range):							
G. Form completed/filled by:							
Name:	Date & Signature:						