

Report Form for Product Complaints and suspected Adverse Effects / Reactions Schülke & Mayr GmbH, Robert-Koch-Str. 2, 22851 Norderstedt, Germany				
Medicinal Product <input type="checkbox"/>	Medical Device <input type="checkbox"/>	Cosmetic Product <input type="checkbox"/>	Biocide <input type="checkbox"/>	Others <input type="checkbox"/>
<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up information to case No.:				
Reporter / Customer information:				
Reporter name (mandatory):				
Customer name (company / contact)				
Customer number				
Order- / Delivery-note number				
Customer address: (street, ZIP, town, country)				
Customer phone / fax / e-mail:				
Product information:				
Product name (mandatory) size / amount / article number:				
Batch-no. or Serial-no. (mandatory in case of product complaints) / Expiry date:				
Description of the complaint / adverse effect / drug reaction (mandatory:) Date of onset / occurrence:				
Product applied / used from – until:				
Has another product been used previously/before? (If yes, which product?)				
Product / Sample	<input type="checkbox"/> will be returned <input type="checkbox"/> is available <input type="checkbox"/> is not available (anymore)			
Patient information in case of suspected adverse effect (AE) / drug reaction (ADR):				
Gender (mandatory):	<input type="checkbox"/> male <input type="checkbox"/> female <input type="checkbox"/> other	Initials:		
Age / Date of birth:		Weight / Height:	kg	cm
Reason for use:		Route of application:		
Further persons affected?	<input type="checkbox"/> yes <input type="checkbox"/> no	If yes, how many?		

Report Form for Product Complaints and suspected Adverse Effects / Reactions Schülke & Mayr GmbH, Robert-Koch-Str. 2, 22851 Norderstedt, Germany
--

Suspected adverse effect (AE) / drug reaction (ADR) information:

Contact details of involved physician / pharmacist (name / address / e-mail / phone / fax):

Progress of adverse effect / drug reaction and therapy: (if applicable, use attachment) Life threatening? ☐ yes ☐ no

Following action was taken: <input type="checkbox"/> surgical intervention <input type="checkbox"/> hospitalisation <input type="checkbox"/> prolongation of hospitalisation <input type="checkbox"/> none of the above	Final outcome of the AE /ADR: <input type="checkbox"/> unknown <input type="checkbox"/> recovered <input type="checkbox"/> not yet recovered <input type="checkbox"/> irreversible damage <input type="checkbox"/> death (date):	Reaction relation to product: <input type="checkbox"/> definitely <input type="checkbox"/> probable <input type="checkbox"/> possible <input type="checkbox"/> unlikely <input type="checkbox"/> not assessable
--	--	---

Further information relevant for case evaluation:
--

e.g. underlying diseases (e.g. allergy, skin diseases), pregnancy, concomitant medication, laboratory data, test results
(if applicable, use attachment)

Who was informed : ☐ manufacturer / ☐ MAH / ☐ local authority / ☐ others:

Received by schülke / contractual partner (name, date, signature):	
---	--

Transfer to:	<input type="checkbox"/> E-mail: complaints@schuelke.com	
---------------------	---	--