

# Adverse Drug Reaction Collection Form

Fill out mandatory items (\*) and complete form with additional information, if possible.

Send filled form to Drug Safety Allergopharma:

**E-Mail: [pharmacovigilance@allergopharma.com](mailto:pharmacovigilance@allergopharma.com)**

**Fax: +49 40 72765252**

You will find this documentation at: [www.allergopharma.com](http://www.allergopharma.com)

Allergopharma GmbH & Co. KG

Drug Safety

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## 1. Reporter Details

<b>Name (*):</b>	<b>Phone (*):</b> Fax: E-Mail:	Reporter is: <input type="radio"/> Physician <input type="radio"/> Relative <input type="radio"/> Pharmacist <input type="radio"/> HCP <input type="radio"/> Patient <input type="radio"/> other: _____
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## 2. Patient Details

Initials: _____ Last name, First name	Date of birth: _____ DD.MM.YYYY	Height: _____ (cm)
<b>Sex (*):</b> <input type="radio"/> male <input type="radio"/> female	Age: _____ (years)	Weight: _____ (kg)

## 3. Suspected Product Details

<b>Product name (*):</b> Allergen composition:  Batch No:	The reaction was observed at a dose of: _____ ml Strength: _____ (1,2,3 or A,B) <input type="radio"/> Standard dose escalation <input type="radio"/> Accelerated dose escalation <input type="radio"/> One-strength dose escalation	Therapy start _____ last administration _____ DD.MM.YYYY DD.MM.YYYY Indication: Route of administration:
Parallel Allergen Immunotherapy? <input type="radio"/> yes <input type="radio"/> no	Product name:	
Date of last administration: _____ DD.MM.YYYY	Allergen composition: Batch No:	

Actions taken on the suspected drug:

Drug discontinued  Dose unchanged  Dose changed: \_\_\_\_\_ ml / strength: \_\_\_\_\_  unknown

## 4. Adverse Drug Reaction Details

Diagnosis (*) (if unknown signs and symptoms)	Start DD.MM.YYYY	End DD.MM.YYYY	Onset after administration	Duration	Outcome (A)	Causality (B)
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

**(A)** Choose: 1 = recovered/resolved, 2 = recovering, 3 = permanent damage, 4 = not recovered/not resolved, 5 = death (date), 6 = unknown

**(B)** Choose: 1 = certain, 2 = probable/likely, 3 = possible, 4 = unlikely, 5 = unassessable/unclassified, 6 = not related, 7 = unknown

Description of reaction::

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## 5. Treatment of Adverse Drug Reaction

Drug	Product name	Dosage	Route of administration
<input type="radio"/> none <input type="radio"/> unknown  <input type="radio"/> Antihistamine  <input type="radio"/> Steroid  <input type="radio"/> $\beta$ -Sympathomimetics  <input type="radio"/> Adrenaline/Epinephrine  <input type="radio"/> Others, e.g. local treatment	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

Did reaction reappear after reintroduction?      Did reaction abate after use stopped or dose reduced?

yes    no    unknown     
  yes    no    unknown

## 6. Seriousness of Reaction

non-serious       serious, please specify:

<input type="radio"/> Death	<input type="radio"/> Hospitalization prolonged
<input type="radio"/> Life-threatening	<input type="radio"/> Permanent or serious disability
<input type="radio"/> Hospitalization	<input type="radio"/> Congenital anomaly / birth defect
<input type="radio"/> Other medically important condition	

## 7. Medical History

none    unknown

	Start date DD.MM.YYYY	End date DD.MM.YYYY	Ongoing
Asthma <input type="radio"/> yes <input type="radio"/> no <input type="radio"/> unknown	_____	_____	<input type="radio"/> yes <input type="radio"/> no
Other diseases: _____	_____	_____	<input type="radio"/> yes <input type="radio"/> no
_____	_____	_____	<input type="radio"/> yes <input type="radio"/> no
_____	_____	_____	<input type="radio"/> yes <input type="radio"/> no

## 8. Concomitant Drug Therapy

none    unknown

Drug	Product name	Dosage	Route of administration	Start date DD.MM.YYYY	End date DD.MM.YYYY	Indication
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

## 9. Has this case been reported?

no       yes, please specify:

<input type="radio"/> directly to Allergopharma	<input type="radio"/> to Allergopharma External sales
<input type="radio"/> Competent Authority	<input type="radio"/> others: _____

Stamp or address: \_\_\_\_\_

Date of report: \_\_\_\_\_      Signature of reporter: \_\_\_\_\_  
 DD.MM.YYYY      (Physician/pharmacist)