Adverse Drug Reaction Collection Form

Allergopharma GmbH & Co. KG
Drug Safety
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Fill out mandatory items (*) and complete form with additional information, if possible.

Send filled form to Drug Safety Allergopharma:

E-Mail: pharmacovigilance@allergopharma.com **Fax: +49 40 72765252**

You will find this documentation at: www.allergopharma.com

Reset Print

1. Reporter Details

Name (*):	**Phone (*):** Fax: E-Mail:	Reporter is: ○ Physician ○ Relative ○ Pharmacist ○ HCP ○ Patient ○ other: _____

2. Patient Details

Initials: _____ _____ Last name, First name **Sex (*):** ○ male ○ female ○ unknown	Date of birth: _____ DD.MM.YYYY Age: _____ (years)	Hight: _____ (cm) Weight: _____ (kg)

3. Suspected Product Details

Product name (*): Allergen composition: Batch No:	The reaction was observed at a dose of: _____ ml Strength: _____ (1,2,3 or A,B) ○ Standard dose escalation ○ Accelerated dose escalation ○ One-strength dose escalation	Therapy start last administration _____ _____ DD.MM.YYYY DD.MM.YYYY Indication: Route of administration:

Parallel Allergen Immunotherapy? ○ yes ○ no

Date of last administration: _____ DD.MM.YYYY

Product name:
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, 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
❍ none ❍ unknown			
❍ Antihistamine			
❍ Steroid			
❍ β-Sympathomimetics			
❍ Adrenaline/Epinephrine			
❍ Others, e.g. local treatment			

Did reaction reappear after reintroduction?
❍ yes ❍ no ❍ unknown

Did reaction abate after use stopped or dose reduced?
❍ yes ❍ no ❍ unknown

6. Seriousness of Reaction

❍ non-serious

❍ serious, please specify:

- ❍ Death
- ❍ Life-threatening
- ❍ Hospitalization
- ❍ Other medically important condition
- ❍ Hospitalization prolonged
- ❍ Permanent or serious disability
- ❍ Congenital anomaly / birth defect

7. Medical History

❍ none ❍ unknown

		Start date DD.MM.YYYY	End date DD.MM.YYYY	Ongoing
Asthma	❍ yes ❍ no ❍ unknown			❍ yes ❍ no
Other diseases:				❍ yes ❍ no
				❍ yes ❍ no
				❍ yes ❍ 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:

- ❍ directly to Allergopharma
- ❍ Competent Authority
- ❍ to Allergopharma External sales
- ❍ others: _____

Stamp or address:

Date of report: _____ DD.MM.YYYY

Signature of reporter: _____ (Physician/pharmacist)

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