PALFORZIA REMS Anaphylaxis Adverse Event Reporting Form

PALFORZIA® is available only through the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy); a restricted program. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program can prescribe, administer, dispense, and receive PALFORZIA.

INSTRUCTIONS:

Anaphylaxis adverse events (including suspected cases managed as anaphylaxis) must be reported to the REMS. If a patient experienced more than one anaphylaxis event, please complete this form for each unique event.

Complete and submit this form to the REMS online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013.

PATIENT INFORMATION *(*indicates required field)*

First Name*:	MI:	Last Name*:
Date of Birth*: (MM/DD/YYYY)	Sex: ☐ Female ☐ Male ☐ Other	Patient REMS ID:
Address 1*:		
Address 2:		
City*:	State*:	ZIP*:

PRESCRIBER INFORMATION *(*indicates required field)*

First Name*:	Last Name*:	National Provider Identifier (NPI #):	Prescriber REMS ID:
Practice/Facility Name:			
Address 1:			
Address 2:			
City:	State:	ZIP:	
Phone Number:	Email Address:		

Anaphylaxis Event Characteristics *(* indicates required field)*

Date of Event*:

Date of start of PALFORZIA:

Current PALFORZIA Dose*:

Date of Start of Current PALFORZIA Dose:

How long after the given dose of PALFORZIA did the symptoms start*: _____ hours _____ minutes ☐ Unknown

Description of clinical course*:

Signs and Symptoms*:

(please check all signs and symptoms that were present during the event; for descriptions see Table 1 "Glossary of Terms"):

General: ☐ Sudden Onset ☐ Rapid progression of signs/symptoms

Body System	Major Criteria	Minor Criteria
Dermatological or mucosal	☐ generalized urticaria (hives) ☐ generalized erythema ☐ angioedema, localized or generalized (not hereditary angioedema) ☐ generalized pruritis with skin rash	☐ generalized pruritis without skin rash ☐ generalized prickle sensation ☐ red, itchy eyes
Cardiovascular	☐ measured hypotension ☐ uncompensated shock as indicated by ≥ 3 of the following: ☐ tachycardia ☐ capillary refill time >3 seconds (s) ☐ reduced central pulse volume ☐ decreased level or loss of consciousness	☐ reduced peripheral circulation as indicated by ≥ 2 of the following: ☐ tachycardia ☐ capillary refill time > 3 s, without hypotension ☐ decreased level of consciousness
Respiratory	☐ bilateral wheeze (bronchospasm) ☐ stridor ☐ upper airway swelling (lip, tongue, throat, uvula, or larynx) ☐ respiratory distress with ≥ 2 of the following: ☐ tachypnea ☐ increased use of accessory respiratory muscles (sternocleidosmastoid, intercostals, etc.) ☐ recession ☐ cyanosis ☐ grunting	☐ persistent dry cough ☐ hoarse voice ☐ difficulty breathing without wheeze or stridor ☐ sensation of throat closure ☐ sneezing, rhinorrhea
Gastrointestinal	Not applicable	☐ diarrhea ☐ abdominal pain ☐ nausea ☐ vomiting
Laboratory	Not applicable	☐ mast cell tryptase elevated above upper limit of normal

Epinephrine availability*:

Was epinephrine available to the patient for immediate use at the time of symptom onset? ☐ Yes ☐ No ☐ Unknown

Treatment of Anaphylaxis Event:

Enter all forms of treatment administered including brand name if known (e.g. epinephrine, antihistamines, steroids, etc.)

Treatment	Dosing and Route of Administration	Number of Doses

Outcomes:

Did this anaphylaxis event result in any of the following? *(check all that apply)*

☐ Emergency Department visit ☐ Hospitalization ☐ Intensive Care Unit admission ☐ Death

Reporter Signature ***(* indicates required field)***

I agree to be contacted to provide additional pertinent information regarding reports of anaphylaxis

Printed Name*:

First Name _____ Last Name _____

☐ **Reporter Signature***

Date* _____

Phone Number*:

Email Address:

aimmune THERAPEUTICS

Phone: 1-844-PALFORZ (1-844-725-3679) **www.PALFORZIAREMS.com** **Fax: 1-844-285-2013**

Palforzia®
Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

Version Date 05/24

Appendix (For reference only. Do not transmit.)

Table 1: Glossary of Terms[1,2]

TERM	DESCRIPTION
Abdominal pain	Sensation of discomfort or pain in the abdominal region
Angioedema	Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. *(Reported symptoms of "swelling of the tongue" or "throat swelling" should not be documented as angioedema unless there is visible skin or mucosal swelling.)*
Capillary refill time greater than 3 seconds	The capillary refill time is the time required for the normal skin color to reappear after a blanching pressure is applied for 5 seconds. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink color returning to the nail. Normally it is less than 3 seconds.
Cyanosis	A dark bluish or purplish discoloration of the skin and/or mucous membranes due to a lack of oxygen in the blood
Diarrhea	Loose or watery stools which may occur more frequently than usual
Dry cough	Rapid expulsion of air from the lungs and not accompanied by expectoration (a non-productive cough)
Erythema	Abnormal redness of the skin without any raised skin lesions
Generalized	Involving more than one body site—that is each limb is counted separately as is the abdomen, back, head and neck.
Grunting	A sudden and short noise with each breath when breathing out
Hoarse voice	An unnaturally harsh cry in an infant or vocalization in a child or adult
Hypotension (measured)	An abnormally low blood pressure documented by appropriate measurement Infants and children—Age specific systolic blood pressure (BP) of less than the 3rd to 5th percentile or greater than a 30% decrease from that person's baseline Adults—Systolic BP of less than 90 mm Hg or greater than 30% decrease from that person's baseline
Localized	Involving one body site only
Loss of consciousness	Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual, or painful stimulus
Nausea	An unpleasant sensation vaguely referred to the upper abdominal region (upper region of the abdomen) and the abdomen, with a tendency to vomit
Pruritis or prickle sensation	An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief
Rapid progression	A conventional clinical term without a specific timeframe; as determined by the clinician
Recession (in-drawing or retractions)	Inward movement of the muscles between the ribs (inter-costal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing
Red and itchy eyes	Redness of the whites of the eyes (sclera) with sensation that provokes the desire to rub and/or scratch to obtain relief.
Reduced central pulse volume	Absent or decreased pulse in one of the following vessels—carotid, brachial or femoral arteries
Rhinorrhea	Discharge of thin nasal mucus
Sensation of throat closure	Feeling or perception of throat closing with a sensation of difficulty breathing
Sneezing	An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose
Stridor	A harsh and continuous sound made on breathing in
Sudden onset	An event that occurred unexpectedly and without warning leading to a marked change in a subject's previously stable condition
Tachycardia	A heart rate that is abnormally high for age and circumstance Infants and children—A heart rate that is above the upper limit expected for age—see Table 2 Adults and adolescents—The term is usually applied to a heart rate above 100 beats per minute

TERM	DESCRIPTION
Tachypnea	Abnormally rapid breathing which is abnormally high for age and circumstance Infants and children—A respiratory rate that is above the upper limit expected for age—see Table 2 Adults—a respiratory rate in excess of 25 breaths per minute
Urticaria (hives)	Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours)
Vomiting	The reflex act of ejecting the contents of the stomach through the mouth
Wheezing	A whistling, squeaking, musical, or puffing sound made on breathing out

Table 2. Upper limit of heart and respiratory rate in order to define tachycardia and tachypnea[2]

Age in years	Heart rate upper limit in beats per minute	Respiratory rate upper limit in breaths per minute
<1 year	160	60
1-2 years	150	40
2-5 years	140	35
5-12 years	120	30
>12 years	100	16

References

1. Rüggeberg JU, Gold MS, Bayas JM, Blum MD, Bonhoeffer J, Friedlander S, de Souza Brito G, Heininger U, Imoukhuede B, Khamesipour A, Erlewyn-Lajeunesse M, Martin S, Mäkelä M, Nell P, Pool V, Simpson N; Brighton Collaboration Anaphylaxis Working Group. Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2007 Aug 1;25(31):5675-84. doi: 10.1016/j.vaccine.2007.02.064. Epub 2007 Mar 12. PMID: 17448577.

2. Gold MS, Gidudu J, Erlewyn-Lajeunesse M, Law B; Brighton Collaboration Working Group on Anaphylaxis. Can the Brighton Collaboration case definitions be used to improve the quality of Adverse Event Following Immunization (AEFI) reporting? Anaphylaxis as a case study. Vaccine. 2010 Jun 17;28(28):4487-98. doi: 10.1016/j.vaccine.2010.04.041. Epub 2010 Apr 29. PMID: 20434547.