**TABLE G17. SAFETY – SCIT - PEDIATRICS**

**SCIT Local Reactions -Reported as patients**

| **Study** | **Allergen** | **Number of patients in arm** | **Number of events and Description** | **% of patients** | **Severity** |
| --- | --- | --- | --- | --- | --- |
| Akmanlar  200013 | Dust mites: Der P and F Rush vs Cluster  Cluster | 18 | 3 patients Local swelling > 3 cm: required adjust dosing | 17% | Moderate |
| Altintas  19992 | Dust mites: Dermatophagoides pteronyssinus | 34 | 5 patients Local swelling > 3 cm: required adjust dosing | 15% | Unspecified |
| Kuna  201117 | Alternaria | 30 | 4 patients /11 reactions (987 injections): Local edema | 13% | Mild |
| Van Bever  19904 | Dust mite | 9 | 1 patients with Local swelling | 11% | Mild |

**SCIT Local Reactions - Reported as events**

| **Study** | **Allergen** | **Number of patients in arm** | **Number of events and Description** | **% of injections** | **Events per Patient** | **Severity** |
| --- | --- | --- | --- | --- | --- | --- |
| Schubert  20095 | Dust mites (cluster schedule)  Dust mites (classic schedule) | 20  (341 injections)  10  (151 injections) | 185 local events:  Redness: 97 (28%), Swelling <5cm: 57 (16%),  Swelling > 5cm: 22 (6%), painful swelling >3h: 8 (2%)  80 local events:  Redness: 40 (26%), Swelling <5cm: 20 (13%),  Swelling > 5cm: 17 (11%), painful swelling >3h: 3 (2%) | 54%  53% | 9.25  8 | Mild  Mild |
| Dreborg  198616 | Cladosporium | 16 | 4 local reactions: defined as reaction > 10 cm diameter | NA | 0.25 | Mild |
| Valovirta  19866 | Dogs  Placebo | 15  12 | 309 local reactions: 227<1cm, 71 1-3cm, 11>3cm  251 local reactions: 163<1cm, 82 1-3cm, 6>3cm | NA  NA | 20  21 | Mild  Mild |

**SCIT Cutaneous reactions - Reported as patients**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study** | **Allergen** | **Number of Patients in arm** | **Number of events and Description** | **% of patients** | **Severity** |
| Dreborg  198616 | Cladosporium | 16 | 3 patients: urticaria | 19% | Unspecified |
| Cantani  199715 | Dermatophagoides pteronyssinus Perennial ryegrass Parietaria officinalis | 151 | 3 patients: urticaria | 2% | Unspecified |

**SCIT Respiratory Reactions - Reported as patients**

| **Study** | **Allergen** | **Number of Patients in arm** | **Number of events and Description** | **% of patients** | **Severity** |
| --- | --- | --- | --- | --- | --- |
| Akmanlar 200013 | Both Der P and F (conventional schedule)  Both Der P and F (rush schedule) | 9  9 | 3 patients bronchospasm  2 patients bronchospasm | 30%  22% | Severe  Severe |
| Cantani 199715 | Multiple: Dermatophagoides pteronyssinus, Perennial ryegrass, Parietaria officinalis | 151 | 2 patients with wheezing | 1% | Unspecified |

**SCIT Respiratory Reactions - Reported as events**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Allergen** | **Number of Patients in arm** | **Number of events and Description** | **% of injections** | **Events per Patient** | **Severity** |
| Schubert 20095 | Dust mites (cluster schedule)  Dust mites (classic schedule) | 20  (341 injections)  10  (151 injections) | 12 reactions: 10 cough-2 dyspnea  2 reactions had bronchial asthma)  7 reactions: 6 cough-1 dyspnea  1 reaction had bronchial asthma) | 3.5%  0.6%  4.6%  0.7% | 0.7  0.8 | Mild  Moderate  Mild  Moderate |

**SCIT Systemic Reactions: General symptoms**

| **Study** | **SLIT Allergen** | **Number of Patients in Arm** | **Description** | **% of patients** | **Severity** |
| --- | --- | --- | --- | --- | --- |
| Adkinson  19978 | Multiple allergens  Placebo | 61  60 | 21 patients with systemic reactions  4 patient with systemic reactions | 34%  7% | Unspecified  Unspecified |
| Kuna  201117 | Alternaria  Placebo | 30  20 | 1 patient reported headache 1 hour after injection that continued up to 5 hours, no treatment given.  2 patients with mild facial flushing and redness with placebo injections | 3%  10% | Mild  Unspecified |

**SCIT Unspecified Reactions - Reported as patients**

| **Study** | **Allergen** | **Number of Patients in Arm** | **Number of events and Description of the reaction** | **% of Patients** | **Severity** |
| --- | --- | --- | --- | --- | --- |
| Hedlin 199914 | Cats Dermatophagoides pteronyssinus White birch Timothy grass (plus pollen extract) | 15 | 5 systemic side effects :  1 patient was excluded due to recurrent asthma and urticaria | 33% | Mild |

**SCIT Unspecified Reactions - Reported as events**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Allergen** | **Number of Patients in Arm** | **Number of events and Description of the reaction** | **% of Injections** | **Events per Patient** | **Severity** |
| Dreborg 198616 | Cladosporium | 16 | 45 unspecified systemic reactions | NA | 2.8 | Unspecified |

**Anaphylactic reactions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study** | **Allergen** | **Number of Patients in arm** | **Number of events** | **Definition of anaphylaxis** |
| No study reported Anaphylactic reactions |  |  |  |  |

**% of patients calculated, % of injections given in the article, NA Not available: means % is not given and can not be calculated as denominator is not given.**