



War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 15: Dermatological Adverse Events of Special Interest Review of 5.3.6

SOURCE:

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

“Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021.”

5.3.6 AE CASES/EVENTS:

TOTAL AE CASES: 42,086

TOTAL AE EVENTS: 158,893

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer’s mRNA COVID-19 vaccine

SEQUELAE: an abnormal condition resulting from a previous disease, injury, or other trauma

AGE GROUPS defined in 5.3.6

(p. 25 footnote) :

Adult	18 - 64
Elderly	≥ 65
Child	2 - 11
Adolescent	12 - < 18
Infant	1 – 23 months

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Dermatological AESIs Search criteria: PT <i>Chilblains</i> : <i>Erythema multiforme</i>	<ul style="list-style-type: none"> Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; Subjects’ gender: female (17) male and unknown (1) each; Subjects’ age group (n=19): Adult (18), Elderly (1); Number of relevant events: 20 events, 16 serious, 4 non-serious
	<ul style="list-style-type: none"> Reported relevant PTs: <i>Erythema multiforme</i> (13) and <i>Chilblains</i> (7) Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>

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This SOC consists of 20 dermatological adverse events. It contains two separate diagnoses: 13 **erythema multiforme**, a distinctive hypersensitivity reaction with target-like lesions involving the skin and mucous membranes, and seven **chilblains**, a localized form of vasculitis affecting mainly fingers and toes.

It is unclear why Pfizer chose not to include **erythema multiforme** in the Immune-Mediated/Autoimmune AESI category, which had over 500 hypersensitivity adverse events. Similarly, **chilblains** were not reported under the “Vasculitis category” of adverse events.

There were 20 total cases. Eighteen of the adverse events occurred in adults and just one in the elderly age group. Age was not provided on the remaining case. Seventeen (94%) of the individuals were female, one was male, and one was of unknown sex.

The two remarkable features of this small group of patients are the **overwhelming ratio of female to male** and the **occurrence in nonelderly adults**. This has been a consistent pattern of adverse events reported in Table 7 of the 5.3.6 Pfizer document.

The median onset was three days after the injection, ranging from under 24 hours to 17 days. Outcomes reported included seven “resolved/resolving”, eight “not resolved”, and six “unknown”.*

Although this Dermatological category is small in numbers, **sixteen (80%) of the adverse events were categorized as serious**. According to the FDA link below, serious adverse events include, but are not limited to, patient outcomes such as death, life-threatening events, hospitalizations, and disability or permanent damage.

<https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>

Despite an **80% “serious” adverse event rate**, Pfizer concludes: “This cumulative case review does not raise new safety issues. Surveillance will continue.”



RECALL this unsafe “vaccine.”

*Pfizer’s 5.3.6 document shows 20 cases and 20 adverse events; however, both sex and outcomes do not add up to 20. Rather, sex is under (19), outcomes are over (21).

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