Shedding Is Real

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FDA REGULATIONS ON GENE THERAPIES

- COVID mRNA "vaccines" are gene therapy products as defined in the FDA's 2015 document on Gene Product Shedding Studies and by a similar European Medicines Agency (EMA) document:

- ***"Gene therapy products are all products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms.***

- The FDA document defines shedding of gene therapy products as:

- ***"The release of viral or bacterial gene therapy products from the patient by any or all of the following routes: feces (feces); secretions (urine, saliva, nasopharyngeal fluids, etc.); or through the skin (pustules, lesions, sores)."***

GENE THERAPY PRODUCTS ALL HAVE SHEDDING AS A RISK IN THEIR INSERTS

- Shedding of LUXTURNA

  Transient and low level shedding of LUXTURNA may occur in patient tears. Advise patients and/or their caregivers on proper handling of waste material generated from dressing, tears, and nasal secretion, which may include storage of waste material in sealed bags prior to disposal. These handling precautions should be followed for up to 7 days following LUXTURNA administration.

Manufactured by:
Spark Therapeutics, Inc.
3737 Market Street
Philadelphia, PA 19104

US License #2056

- Roctavian was found to shed into semen and the FDA advises those who receive it to **not donate semen or impregnate someone** for at least 6 months after administration.

- Another gene therapy product called Zolgensma was also found to shed for a month, and its package insert advises that during this time, to be **careful of how feces from the patients are disposed of to avoid exposure to others.**

PFIZER KNEW THE RISKS OF SHEDDING

- From their own trial protocol, p. 67: “the investigator is **instructed to report** various "environmental exposures" as follows:
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1) “A **male participant who is receiving** or has discontinued study intervention **exposes a female partner prior to or around the time of conception."**
2) “A female family member or healthcare provider reports that **she is pregnant after having been exposed to the study intervention by inhalation or skin contact**."
3) "A male family member or healthcare provider **who has been exposed to the study intervention by inhalation or skin contact** then exposes his female partner prior to or around the time of conception" (note this refers to “secondary shedding” as defined later in the document)
4) **"A female is found to be breastfeeding while being exposed or having been exposed to study intervention** (i.e., environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been **exposed to the study intervention by inhalation or skin contact."**

The mRNA Vaccine Also Falls Under The Category Of "Nanoparticle Technology"

- Nanoparticles exist in both natural, biological forms (called exosomes) and synthetic
- The mRNA in the vaccines is delivered to the cell within synthetic lipid nanoparticle (LNPs).
- Synthetic mRNA vaccine LNPs have the same structure as the natural exosomes they seek to mimic
- Exosomes are tiny extracellular vesicles of endosomal origin, typically 30-150 nm in diameter, containing a complex cargo of contents derived from the original cell, including proteins, lipids, mRNA, miRNA, and DNA.
- They are formed through the fusion and exocytosis of multivesicular bodies into the extracellular space.
- Exosomes are constantly produced by all cells in vitro and in vivo and are changing research due to their interesting functions within the human body, including inter-cellular communication and signaling.

Nanoparticles Continued

- Exosomes form a critical communication network the body relies upon (e.g., mothers have exosomes in their breastmilk, which make it through the digestive tract and deliver mRNA to their developing babies playing a critical epigenetic role in guiding their healthy development).

- As a gene therapy, the mRNA vaccines work by delivering mRNA within synthetic LNPs into the cell, which instructs the cell to make spike protein. The spike protein is then pushed to the cell surface at which point they bud off into exosomes that traverse the body.

- A critically important aspect of exosomes and LNPs **is that they can cross the biological barriers shielding various parts of the human body,** such as the blood-testes barrier and enter the testes in animal models. Another review paper stated: **"these ultrafine particles are capable of entering the body through skin pores, debilitated tissues, injection, olfactory, respiratory and intestinal tracts."**

Mechanisms Of Shedding

- Three Conditions Must Be Met:

- **Condition #1**: The produced spike protein would need to distribute widely in the body in order to allow excretion via the breath, urine, sweat, breast milk, feces etc.

- **Condition #2**: The spike protein would need to establish sufficient concentration in body fluids or exhaled breath.

- **Condition #3**: LNPs and/or spike protein-containing exosomes must be able to enter the body of an exposed person either through inhaled breath, skin, or eyes.
  - If pregnant, LNP/exosomes would need to have the ability to cross the placenta.
  - For breastfeeding women, exosomes with free spike protein or mRNA would need to be found in breast milk

Shedding Condition #1: The produced spike protein would need to distribute widely in the body in order to allow excretion via the lungs, urine, sweat, breast milk, feces, etc.

1) Synthetic LNPs containing vaccine mRNA are distributed widely in the body as per this recently leaked EMA letter.

2) A Japanese document obtained by FOIA reported on the lipid nanoparticle biodistribution data for Pfizer's vaccines and found the LNPs distribute to every organ in the body.

1) Australia's Therapeutics Goods Administrations (TGA) evaluation report on Pfizer's nonclinical biodistribution study also revealed that the lipid nanoparticles travel to the liver, spleen, brain, eyes, bone marrow, adrenal glands, ovaries, and testes.

Shedding Condition #2: The spike protein would need to be present in exosomes in sufficient quantities in body fluids or exhaled breath. For pregnant women, spike protein would need to be found in breast milk.

- The spike protein has a high (heparin dependent) affinity for binding to the surface of exosomes and numerous studies find that significant amounts of spike protein containing exosomes (which circulate in the bloodstream) increase rapidly after vaccination (and then decline). Other papers from 2013, 2020 and 2021 show that **significant amounts of RNA containing exosomes can be found in breath.**

- Numerous studies have found that vaccination with mRNA and translation of the mRNA induces the **production of exosomes carrying the spike protein and circulating in the blood** for a diverse range of durations (more than a week, up to 15 days up to **4 months**, and up to 187 days [the study ended so the maximal duration has not yet been established]).

- Evidence for the biologic activity of spike protein-coated exosomes can be found in this study, which found that after COVID infection, **spike protein-coated exosomes trigger an immune response in lung cells exposed to the exosomes.**

Studies Demonstrating Vaccine Product Persistence

Table 1. Studies demonstrating persistence of vector-based vaccine constituents and/or derivative spike protein.

Author	Constituents/Tissue Type/Assay Technique	Duration Measured
Animal		
Pfizer (Japanese MoH) 2020 [46]	Radiolabelled LNP in plasma and tissues	140 h–14 days
Human		
Ogata et al. (2021) [52]	Spike protein and S1 subunit (assay)	3 days
Bansal et al. (2021) [57]	Spike Protein	4 months
Fertig et al. (2022) [50]	LNPs and mRNA	15 days
Röltgen et al. (2022) [53]	mRNA and Spike Protein in ipsilateral lymph nodes; 2–7 days post dose in blood	60 days
Yamamoto et al. (2022) [58]	Spike Protein in skin	3 months
Yonker et al. (2023) [54]	Spike Protein in blood	1–19 days *in cases of myocarditis*
Castruita et al. (2023) [51]	mRNA in plasma	28 days

More Evidence of Disseminated Spike

CASE REPORT:

- Clinical and pathologic evidence are available as well: a case report of an autopsy done in a man who died of multifocal necrotizing encephalitis three weeks after the vaccine found vaccine spike in numerous organs (heart, brain, muscles, germinal centers etc.). Further, they emphasized the finding of high concentrations in the walls of capillaries.

AUTOPSY SERIES

- A team led by the esteemed senior German pathologist, Arne Burkhart, stained autopsy specimens for the presence of spike protein. He presented their findings in multiple invited lectures and reported that **out of the first 50 autopsies performed at the request of families who suspected their loved one's death was due to the vaccine, in 80% of cases spike-induced organ damage was determined to be the proximate cause of death.**

Shedding Condition #3: Spike protein containing exosomes must be able to enter the body through inhaled breath, or eyes. If pregnant, exosomes would need to have the ability to cross the placenta. For breastfeeding women, spike protein or mRNA would need to be found in breast milk and be able to be absorbed via the baby's GI tract.

- **The inhalation route presents the highest risk of absorbing shed gene therapy-based vaccine products**. The findings in this paper from 2005 states that:

- *"When inhaled, specific sizes of nanoparticles (LNP's/exosomes) are **efficiently deposited by diffusional mechanisms in all regions of the respiratory tract. The small size facilitates uptake into cells and transcytose across epithelial and endothelial cells** into the blood and lymph circulation to reach potentially sensitive target sites such as bone marrow, lymph nodes, spleen, and heart."*

- A 2023 peer-reviewed study found that unvaccinated individuals who were around COVID-19 vaccinated individuals developed an immune response to the spike protein.

PUBLISHED EVIDENCE SUPPORTING SHEDDING VIA BREAST MILK

- This study found that the **vaccine mRNA was found in the milk of 1/10 women** studied (4/40) in the first week after vaccination with mRNA vaccine (either after dose 1 or dose 2). Amounts can reach 2 ng/mL of milk.
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- This study in the Lancet found trace amounts of mRNA in 7 samples from 5 different participants at various times up to 48 hours post vaccination. The **vaccine mRNA appeared in higher concentrations in the extracellular vesicles (i.e. exosomes/nanoparticles**) than in whole milk. Their conclusion:

- *"Our findings demonstrate that the **COVID-19 vaccine mRNA is not confined to the injection site** but spreads systemically and is packaged into breast milk extracellular vesicles."*

CAN BABIES ABSORB VACCINE PRODUCTS VIA THE GI TRACT?

- I initially reasoned that the stomach acid of the baby would destroy the mRNA and render it inert.

But then we found these papers (here, here, and here), which stated:

- "*It has been known for some years that **mRNA encapsulated in extracellular vesicles is protected from gastric juices and can transfect intestinal cells.** A recent review by Melnik and Schmitz confirms that milk EVs survive the extreme conditions of the gastrointestinal tract, are internalized by endocytosis, are bioavailable, reach the bloodstream, and penetrate peripheral tissue cells. Beyond integration into the genome, other concerns should arise such as provoking an "immunogenic" reaction to mRNA."*

ADVERSE EVENTS FOR BREAST FED BABIES

16.3.3.1.16. Stroke

- Search Criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents; Cerebrovascular venous and sinus thrombosis (Primary Path).

  - Upon review, 2 PM cases were determined to be non-contributory and are not included in the discussion since these 2 cases involved babies who were indirectly exposed to BNT162b2 (trans-mammary route).

BREAST FEEDING ADVERSE EVENTS CON'T

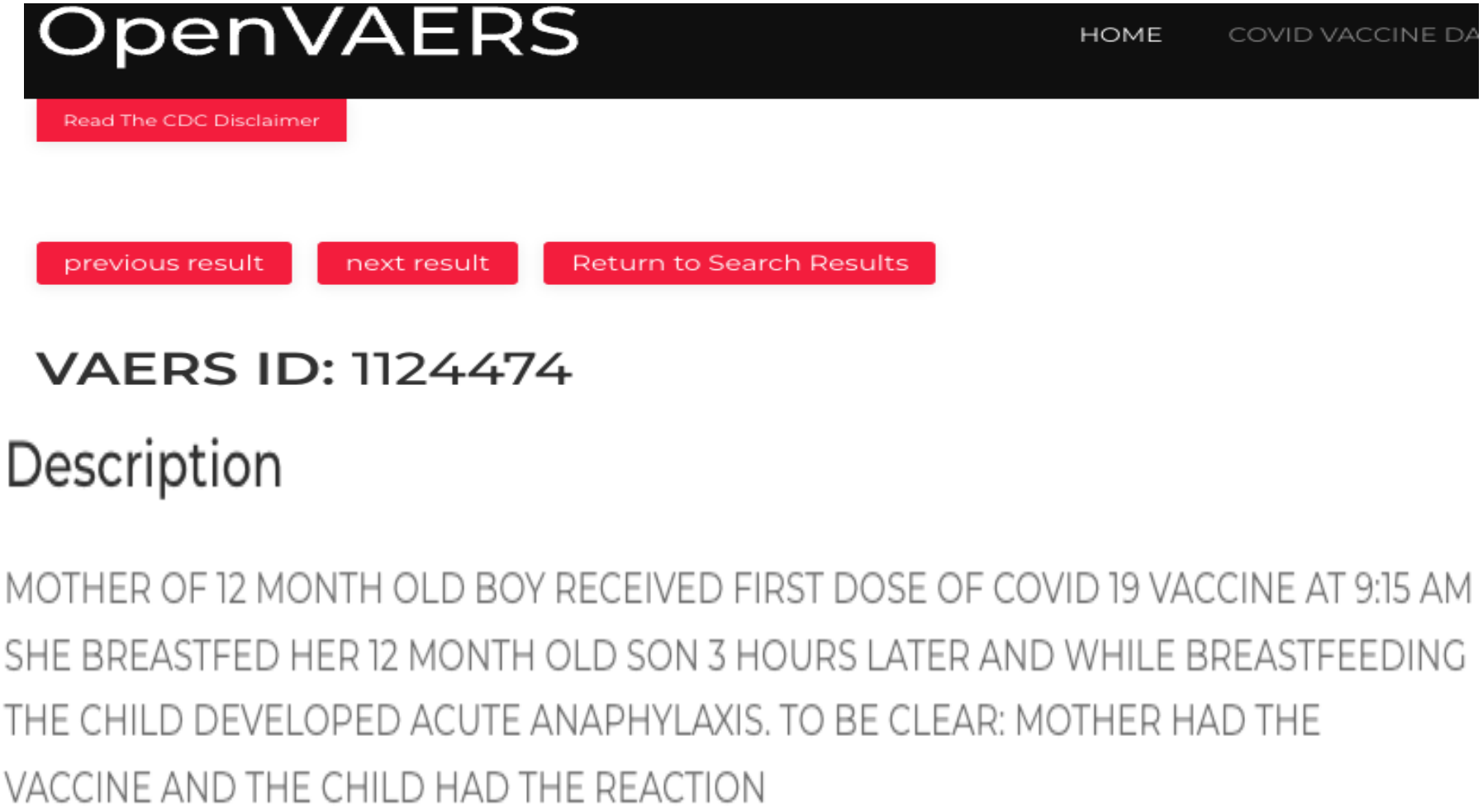
- Convulsions?

16.3.3.1.10. Neurological AESIs (including demyelination)

- Search Criteria: SMQ Convulsions (Narrow and Broad) OR SMQ Demyelination (Narrow and Broad) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Neuropathy peripheral; Polyneuropathy.

  - Upon review, 3 PM cases were determined to be non-contributory and are not included in the discussion since these 3 cases involved babies who were indirectly exposed to BNT162b2 (trans-mammary route).

ANAPHYLAXIS?



RESPIRATORY FAILURE?

16.3.3.1.16. Respiratory AESIs

Search criteria - HLTs (All Path) Lower respiratory tract infections NEC; Respiratory failures (excl neonatal); Viral lower respiratory tract infections OR PTs Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Respiratory disorder.

Upon review, 4 cases were determined to be non-contributory and were not included in the discussion since these cases involved exposures to the vaccine during the mother's pregnancy or through breastfeeding.[99]

SKIN EXFOLIATION?

Preferred Term	Number of Events
Rhinorrhoea	1
Roseola	1
Skin exfoliation	1
Vision blurred	1

There were 10 SAEs reporting with the PT Exposure via lactation. Six of these SAEs were reported in infants.

- A 15-month old infant with medical history of vomiting experienced skin exfoliation and infant irritability while being breastfed (latency <7 days). The outcome of the event 'skin exfoliation' was not recovered and outcome of event 'infant irritability' was unknown. No causality was reported by the physician.

TRANSPLACENTAL – Proportional Reporting Ratios

- "Abnormal menses" ranges from an **RR of 298 to 4927 (i.e. well over the threshold of 2)**. With miscarriages, the PRR ranges from 15-57.

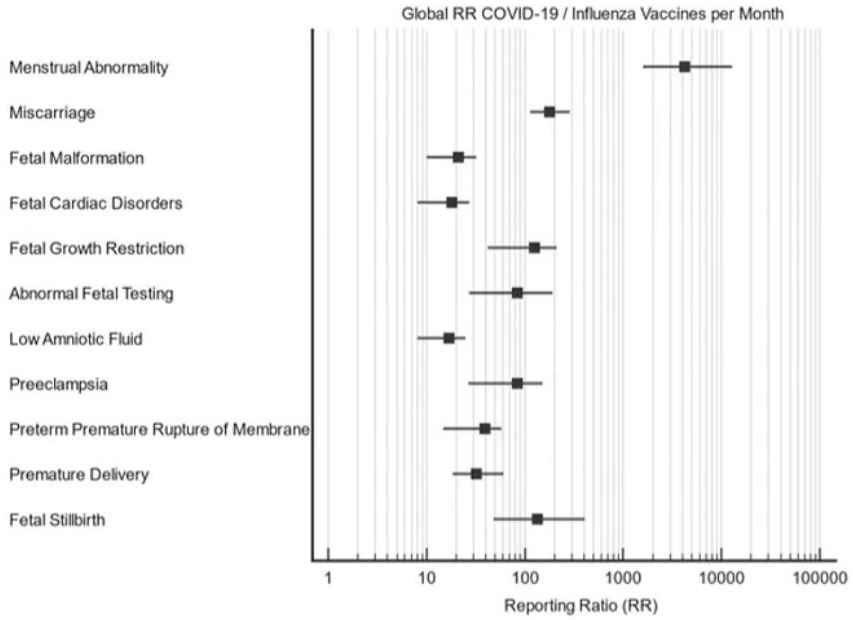


Figure 2. Global Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Month.

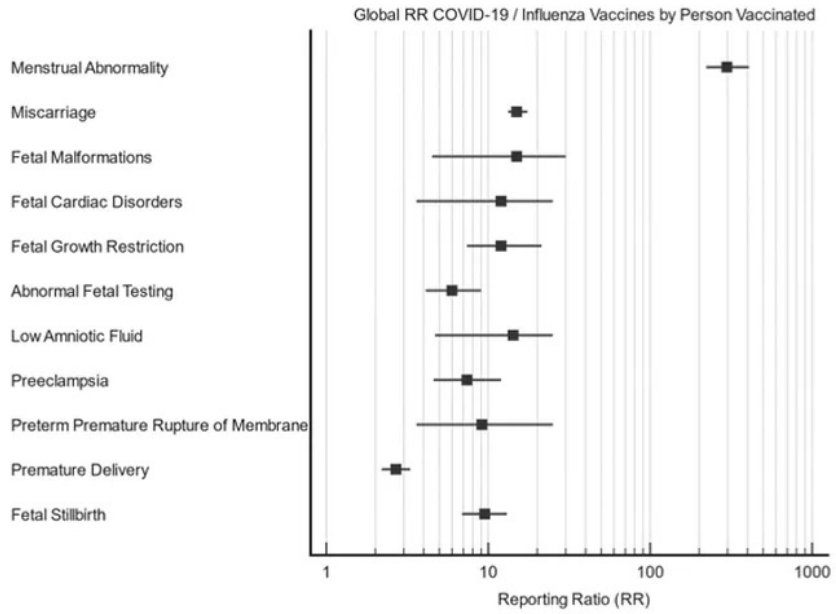


Figure 3. Global Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Persons Vaccinated

Thorpe et al, 2023

Evidence For Person To Person Shedding – taken from A Midwestern Doctor "The Forgotten Side of Medicine"

- A 2023 peer-reviewed study found that unvaccinated individuals who were around COVID-19 vaccinated individuals developed an immune response to the spike protein
- Most worrying is a paper which found that excess **mortality amongst unvaccinated young people spiked for the first 18 weeks after the adult mRNA campaign rollout**

- We and others (e.g., My Cycle Story) made a public call for reports of shedding phenomena. We have currently compiled over 800 reports. Although **many may dismiss these as "anecdotal" data**, we disagree:
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1. The descriptions submitted were **repeatable and predictable**;
2. The descriptions appeared **evenly split between people who reported a cluster of symptoms vs. a single symptom**;
3. Many submissions were by people who **only realized they were being affected by shedding once they saw that what they had experienced matched what many others reported.**

SUMMARY OBSERVATIONS OF OVER 1000 CLINICAL REPORTS OF SHEDDING

- **Patterns Of Shedding**
  - **Primary** (where someone gets ill from being around a vaccinated person (e.g. vaccinated parents making their unvaccinated children ill)
  - **Secondary** where someone gets ill from being around a person who was recently around vaccinated people, (e.g., children shedding and affecting parents after coming back home from school).

- **Susceptible Patients**
  - Sensitivity to shedding varies immensely and **generally only affects environmentally or physiologically sensitive** people
  - **Symptoms resemble what is seen in other spike protein-induced syndromes** (e.g., long COVID/long Vax).
  - Patients develop **similar symptoms after a shedding exposure**, particularly after a “strong” shedding exposure
  - Many patients reported **repeated shedding symptoms emerge after the same exposure**

“Sensitive Patients”

- Highly sensitive to toxins in their environment
- Very empathetic and perceptive of subtle qualities others do not notice;
- Have an ectomorph body type
- Frequently have ligamentous laxity
- Frequently have chronic illnesses such as mast cell degranulation disorder, multiple chemical sensitivities, EMF sensitivities, Lyme disease, mold toxicity and fibromyalgia
- Were more likely to avoid the COVID vaccine (due to their previous bad experiences with pharmaceuticals)
- Some were more likely to be chronically debilitated by the COVID vaccine (or a COVID-19 infection);

Characteristics Of “Shedders”

- dramatically more likely to shed soon after vaccination (the very sensitive claim they are susceptible far beyond a 2-4 week period)
- shedding events (in the same location) are the most frequent and severe immediately following a new booster rollout
- young and healthy people tend to shed more frequently
- shedding greatly varies by the individual (e.g., “I react to specific people I see at church”).

MOST COMMON SYMPTOMS

- Menstrual abnormalities (by far)
- Decidual Cast shedding
- Headaches
- Tinnitus
- Nosebleeds
- Painless, inexplicable bruising
- Dizziness
- Brain Fog/Malaise
- Skin Rashes

LESS COMMON SYMPTOMS

- Atrial Fibrillation
- Muscle Pain
- Seizures
- Peripheral Neuropathy
- Insomnia
- Hair Loss
- Swollen Lymph Nodes
- Severe abdominal pain
- Sinus Pressure/Copious discharge
- Vision/Eye Problems

RARE SYMPTOMS

- Stroke
- Blood clots
- Severe heart injuries in children
- Polymyalgia Rheumatica
- Death
- Cancers
- Sensory Neuropathy
- Anxiety