

Allergic Reactions Including Anaphylaxis following COVID-19 Vaccines

Ensure that appropriate medical treatment and supervision are readily available to manage anaphylaxis (e.g. [adrenalin](#))

Risk stratification before the first dose

DO NOT VACCINATE BEFORE REFERRAL TO AN ALLERGIIST

- 1) History of **diagnosed** immediate allergic reaction of any severity to polyethylene glycol [PEG] or to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
- 2) Hypersensitivity to the active substance or to any of the excipients of COVID-19 vaccines*
- 3) History of any anaphylaxis and quincke oedema **TO VACCINES**

HIGH PRECAUTIONS

1) VACCINATION IN HOSPITAL SETTING

Idiopathic anaphylaxis
Systemic mastocytosis
Hereditary angioedema

HIGH PRECAUTIONS

2) VACCINATION **OUTSIDE** HOSPITAL SETTING
Close observation for at least 30 minutes

History of anaphylaxis and quincke oedema
(non vaccines)
Severe uncontrolled asthma

STANDARD PRECAUTIONS

VACCINATION **OUTSIDE** HOSPITAL SETTING
Close observation for at least 15 minutes

Allergic/immune diseases
with very low risk for vaccination

Chronic Spontaneous urticaria
Respiratory allergy
Atopic dermatitis
Controlled asthma

History of immediate allergic reactions
(excluding anaphylaxis) to
food, hymenoptera, latex,
drug not containing PEG or polysorbate

In case of symptoms of immediate hypersensitivity after the first dose: blood sampling for tryptase and complement between 60-180 minutes after onset of symptoms is strongly recommended

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Version approved by the NITAG Vaccination during the session of 25/03/2021

Allergic Reactions Including Anaphylaxis following COVID-19 Vaccines

Ensure that appropriate medical treatment and supervision are readily available to manage anaphylaxis (e.g. **adrenalin**)

Risk stratification after the first dose

For practical reasons : if first dose occurs in hospital or in an allergist department, then second dose could also be administered in the same location

DO NOT VACCINATE BEFORE REFERRAL TO AN ALLERGIST

*to ascertain the culprit and recommendation
for other vaccines*

Severe allergic reaction
(anaphylaxis and quincke oedema)
after a previous dose of an COVID-19
vaccine or any of its components*

Negative advice from an allergist in
case of a non-anaphylactic event

HIGH PRECAUTIONS

1) VACCINATION IN HOSPITAL SETTING

Symptoms typical of immediate hypersensitivity (anaphylaxis and quincke oedema) appearing more than **6 hrs after** the first dose

In case of suggestive history of immediate hypersensitivity but negative allergy testing (inconclusive advice)

HIGH PRECAUTIONS

2) VACCINATION **OUTSIDE** HOSPITAL SETTING

Close observation for at least 30 minutes

Patients with immediate non-anaphylactic hypersensitivity: allergy consult and vaccinate in case of positive advice

STANDARD PRECAUTIONS

VACCINATION **OUTSIDE** HOSPITAL SETTING
Close observation for at least 15 minutes

No symptoms

Symptoms not related with hypersensitivity

(Large) local reactions

In case of symptoms of immediate hypersensitivity after the first dose: blood sampling for tryptase and complement between 60-180 minutes after onset of symptoms is strongly recommended

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* LIST OF EXCIPIENTS

Pfizer/ BioNTech – COMIRNATY®: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315); 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159); 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC); Cholesterol; Potassium chloride; Potassium dihydrogen phosphate; Sodium chloride; Disodium phosphate dihydrate; Sucrose.

Moderna – COVID-19 Vaccine Moderna: Lipid SM-102; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG); Cholesterol; Tromethamo; Tromethamol hydrochloride; Acetic acid; Sodium acetate trihydrate; Sucrose.

Vaxzevria (previously COVID-19 Vaccine AstraZeneca): L-histidine; L-histidine hydrochloride monohydrate; sodium chloride; magnesium chloride hexahydrate; disodium edetate dihydrate (ethylenediaminetetraacetic acid, EDTA); sucrose; ethanol; polysorbate 80 ions.

COVID-19 Vaccine Janssen: Sodium chloride; Citric acid monohydrate; Trisodium citrate dihydrate; Polysorbate-80; 2-hydroxypropyl- β -cyclodextrin (HBCD); Ethanol; Sodium hydroxide; Hydrochloric acid.

DRUGS WITH POLYSORBATE 80 (non exhaustive)

Alfa-RIX-tetra (2020-2021), Havrix, Gardasil, Prevenar13, Revaxis, Triaxis-polio, Boostrix-Polio, Imovax-Polio

Diprofos

Xgeva, Taxotere, Ecalta

Lantus/Apidra/Trulicity

Neulasta

Cordarone ampule (IV)

Majority of monoclonal immunoglobulins (bv Mabthera, Remicade)

Macrogol (after colonoscopy preparation e.g.)

Depo-Medrol / Depo-Provera / Depo-Medra

DECISION TREE FOR VACCINATION AGAINST SARS-CoV-2

BEFORE THE 1st DOSE

History of **diagnosed** immediate allergic reaction of any severity to polyethylene glycol [PEG] or to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

Hypersensitivity to the active substance or to any of the excipients of COVID-19 vaccines*?

History of any anaphylaxis and quincke oedema **TO VACCINES?**

YES

**DO NOT VACCINATE
BEFORE REFERRAL TO AN ALLERGIST**

NO

Idiopathic anaphylaxis?

Systemic mastocytosis?

Hereditary angioedema?

YES

VACCINATION IN HOSPITAL SETTING

NO

History of anaphylaxis and quincke oedema (non vaccines) ?

Severe uncontrolled asthma ?

YES

VACCINATION OUTSIDE HOSPITAL SETTING
Close observation for at least 30 minutes

NO

Allergic/immune diseases with very low risk for vaccination ?

Chronic Spontaneous urticaria

Respiratory allergy

Atopic dermatitis

Controlled asthma

History of immediate allergic reactions (excluding anaphylaxis) to food, hymenoptera, latex, drug not containing PEG or polysorbate

YES

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Close observation for at least 15 minutes

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AFTER THE 1st DOSE

For practical reasons : if first dose occurs in hospital or in an allergist department, then second dose could also be administered in the same location

