Medicines & Healthcare products Regulatory Agency

MHRA

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Dear

Local Identification Number:
Patient Initials: Patient Age: Patient Sex:
Yellow Card Reference Number:

Thank you for taking the time to complete a Yellow Card report on a suspected side effect following a COVID-19 vaccine.

In view of the nature of the reaction you reported, please would you be kind enough to provide us with some additional details. In particular, it would be helpful if you could complete the follow up form provided at the end of this letter.

You can return this information to us via email at yellowcard@mhra.gov.uk or call our Yellow Card Information Service on 0808 100 3352 (9am to 5pm Monday-Friday). Please quote the above Yellow Card reference number with all correspondence.

We are working closely with national experts to evaluate the data that you have provided.

All information provided is held in strict confidence and handled in line with our Yellow Card Privacy Policy, which can be found at https://yellowcard.mhra.gov.uk/privacy-policy/. If you wish to request a copy of the information we hold on your case or a copy of your report as it appears in our database, please write to us at the address above or email yellow.card@mhra.gov.uk citing your case reference number and details of your request.

Your contribution to the UK's Adverse Drug Reaction Reporting Scheme is greatly appreciated. This provides an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of medicines.

You can find out more about the suspected Adverse Drug Reactions we have received at www.mhra.gov.uk/yellowcard.

Additionally, you can stay up to date on the latest advice for the safe use of medicines by reading our monthly bulletin Drug Safety Update, which is available on our website at www.gov.uk/drug-safety-update. You can receive a notification of each new bulletin by sending your email address to registration@mhradrugsafety.org.uk.

Yellow Card

Submit Yellow Cards and view further information online at www.mhra.gov.uk/yellowcard

Download the Yellow Card App for free now.
Available on iOS and Android

Yours sincerely,

Vigilance and Risk Management of Medicines

Please complete the follow up form, below.

Further Information on Patients with Thrombotic Event / Thombocytopenia

Source of information			
Name of the person reporting		Position (e.g. specialty and grade)	
Hospital / Practice		Email address	

Patient Details			
Patient Initials:		Local Identification Number:	
Sex:		Yellow Card Reference Number:	
Age:		Ethnicity:	

Patient Background	
Past Medical History:	
Regular and recent medications:	
Previous reactions to medications, especially heparin or anticoagulants	Yes/ No/ Unsure
Infectious illness in the last six weeks:	Yes/ No/ Unsure
Other vaccination received in the last six weeks:	Yes/ No/ Unsure
History of thromboembolic disease, including deep vein thrombosis, pulmonary embolism and cerebral venous sinus thrombosis	Yes/ No/ Unsure
Previous arterial thrombosis, including ischaemic stroke, myocardial infarction or acute coronary syndrome	Yes/ No/ Unsure
History of thrombocytopenia	Yes/ No/ Unsure
History of confirmed or suspected autoimmune or inflammatory disease, including vasculitis	Yes/ No/ Unsure
History of liver disease	Yes/ No/ Unsure
History of renal disease	Yes/ No/ Unsure
History of malignancy	Yes/ No/ Unsure
History of neurological/neurosurgical procedure, including lumbar puncture	Yes/ No/ Unsure
Obesity (BMI ≥30)	Yes/ No/ Unsure
Current smoker	Yes/ No/ Unsure
Pregnancy	Yes/No/ Unsure
If Yes to any above, please provide details:	
Patient's Covid-19 Status	

Previous diagnosis of Covid-19:	Yes, once/ Yes, more than once/ No/ Unsure
If Yes, date of onset:	Date:
If Yes, means of diagnosis:	PCR/ Antibody/ Antigen/ Clinical
If yes, severity of illness	Asymptomatic/ Symptoms self-managed/ Sought medical advice/ Admitted to hospital/ Required respirataory support in hospital

Vaccination Details	
1st vaccination: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Other- specify: Lot number: _____ Dose: ____ Route of administration:	Date:
2nd vaccination: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Other- specify: Lot number: _____ Dose: ____ Route of administration:	Date:
Date of onset of symptoms relating to thrombosis or thrombocytopenia	Date:

Case Definition	
Venous or arterial thrombosis If Yes, Date of onset of clinical features: __/__/____ Date of diagnosis: __/__/____	Yes/No/Unsure
Was there associated thrombocytopenia <150 × 10^9/L If Yes, Date of onset of clinical features (if any): __/__/____ Date of diagnosis: __/__/____	Yes/No/Unsure

Clinical Features – Cerebral Venous Sinus Thrombosis
Time from onset to peak symptoms: _____
Method of diagnosis: CT venogram/ MR venogram/ plain CT head/ plain MR head/ Other- specify: _____
Location: Right-sided/ Left-sided/ Bilateral
Specific location (select all that apply): Superior sagittal sinus/ Inferior sagittal sinus/ Lateral sinus/ Cavernous sinus/ Straight sinus/ Other- specify: _____

Clinical Features – Pulmonary Embolism
Time from onset to peak symptoms: _____
Method of diagnosis: CT pulmonary angiogram/ VQ scan/ Other- specify: _____
Type: Subsegmental/ Segmental/ Lobar/ Saddle/ Unsure/ Other- specify: _____
Co-existing deep vein thrombosis: Yes/ No/ Unsure If Yes, when diagnosed: _____ Location: Upper limb(s)/ Lower limb(s)
Has the patient experienced a similar event before? Yes/ No/ Unsure If Yes, please provide details, including the date and suspected aetiology:

Clinical Features – Arterial Thrombosis
Location of thrombosis: _____
Time from onset to peak symptoms: _____
Method of diagnosis: Ultrasound/ CT scan/ Other- specify: _____

Relevant symptoms and signs, including systemic features:
Treatment: Anticoagulation alone/ Systemic Thrombolysis/ Local catheter-thrombolysis/ None- reason: _____/ Unsure/ Other- specify: _____
Has the patient experienced a similar event before? Yes/No/Unsure If Yes, please provide details, including the date and suspected aetiology:

Clinical Features & Laboratory Results – Thrombocytopenia
First platelet count **after** vaccine: _____ × 10^9/L (usual normal range 150-450) Date: __/__/____ Further details, e.g. remarks from laboratory, or reason if not available: _____
Lowest platelet count **after** vaccine: _____ × 10^9/L (usual normal range 150-450) Date: __/__/____ Further details, e.g. remarks from laboratory, or reason if not available: _____
Last platelet count **before** vaccine if known: _____ × 10^9/L (usual normal range 150-450) Date: __/__/____ Not available/ further details: _____
Bleeding: Yes/ No/ Unsure If Yes, location(s) and severity and need for treatment: _____
Bruising: Yes/ No/ Unsure. If Yes, location: _____
Fever: Yes/ No/ Unsure
Splenomegaly: Yes/ No/ Unsure
Review by haematologist: Yes/ No/ Unsure If Yes, diagnosis or differential diagnoses: _____
Other relevant symptoms and signs, including systemic features:

Laboratory studies	
HIT assay – ELISA	Normal/ Unknown/ Not Done/ Abnormal
HIT assay – functional e.g. AcuStar	Normal/ Unknown/ Not Done/ Abnormal
Thrombophilia screen	Normal/ Unknown/ Not Done/ Abnormal
Lupus anticoagulant	Normal/ Unknown/ Not Done/ Abnormal
Anti-β2 glycoprotein-1 antibody	Normal/ Unknown/ Not Done/ Abnormal
Jak2 mutation or other MPN mutation	Normal/ Unknown/ Not Done/ Abnormal
Factor V Leiden mutation	Normal/ Unknown/ Not Done/ Abnormal
G20210 A prothrombin gene mutation	Normal/ Unknown/ Not Done/ Abnormal
COVID-19 serology or PCR	Normal/ Unknown/ Not Done/ Abnormal
Coagulation screen: PT	Normal/ Unknown/ Not Done/ Abnormal
APPT	Absent/ Unknown/ Not Done/ Present
Fibrinogen	Absent/ Unknown/ Not Done/ Present
D Dimers	Absent/ Unknown/ Not Done/ Present
Details of any abnormal findings: radiology investigations	

Please describe if any of the findings could explain the aetiology of the event:

Treatment (including dose and duration)

Patient outcome
Date of last follow-up (if none, write none):
Maximum level of care required: Outpatient/ Medical Inpatient/ High Dependency Unit/ Intensive Care Unit
Patient alive at last follow-up: Yes/ No If No, was the thrombotic event or thrombocytopenia included on the death certificate: Yes/ No/ Unknown If relevant, date of death:
Outcome at least follow up (circle): Complete resolution / Incomplete resolution / No improvement / Re-occurrence / Other sequalae If relevant, time to complete resolution:_____