

Report Overview - GB-MHRA-ESUSAR-215840423001-00111684

Submission Details

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| ▶ Submitted by: | Prof Richard Haynes |
| ▶ Submission date: | 15/11/2021 |

1. Trial Information

- | | |
|---------------|---|
| ▶ Reference: | SUSAR 021 |
| ▶ Trial Name: | 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy |

2. Patient Details

- | | |
|---|----------|
| ▶ Patient gender: | Female |
| ▶ Patient age at time of the side effect: | 72 Years |
| ▶ Patient Identification Number: | 1447583 |

Chronic kidney disease stage 4

- | | |
|---------------|-----|
| ▶ Continuing: | Yes |
|---------------|-----|

Chronic obstructive airways disease

- | | |
|---------------|-----|
| ▶ Continuing: | Yes |
|---------------|-----|

Type 2 diabetes mellitus

- | | |
|---------------|-----|
| ▶ Continuing: | Yes |
|---------------|-----|

Hypertension

- | | |
|---------------|-----|
| ▶ Continuing: | Yes |
|---------------|-----|

Gout

- | | |
|---------------|-----|
| ▶ Continuing: | Yes |
|---------------|-----|

Transient ischaemic attack

- | | |
|---------------|----|
| ▶ Continuing: | No |
|---------------|----|

Myelodysplastic syndrome

- | | |
|---------------|-----|
| ▶ Continuing: | Yes |
|---------------|-----|

Pulmonary embolism

- | | |
|---------------|----|
| ▶ Continuing: | No |
|---------------|----|

Obstructive sleep apnea syndrome

‣ Continuing: Yes

Osteoarthritis

‣ Continuing: Yes

3. Suspect Reactions**Date sponsor was made aware of the SUSAR:**

12/11/2021

Country of Origin:

United Kingdom

Narrative:

Admitted to hospital on 4th November 2021 with COVID-19 pneumonitis requiring 35% supplemental oxygen. On 5th November dexamethasone, intravenous co-amoxiclav and enoxaparin 20mg were started. On 8th November sarilumab 400mg and Ronapreve 2400mg were administered. On 9th November she consented to join RECOVERY and was randomised to receive baricitinib 2mg on alternate days (dose adjusted because of renal impairment), and she received her first dose at 8.30am on 10th November. At 11am on 11th November she had a witnessed tonic-clonic seizure which self-resolved after a few minutes. No cause of the seizure was apparent, but due to the temporal relationship with baricitinib this was discontinued. A CT head showed no acute pathology. As of 15th November she has had no further seizures.

Seriousness

‣ Other

Generalized tonic-clonic seizure

‣ Reaction Outcome: Not Recovered
‣ Start date: 11/11/2021
‣ End date: 11/11/2021

Brain computerised tomography

‣ Result: No acute pathology demonstrated

4. Suspect Medicines**ALFACALCIDOL**

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 500 ng nanogram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Vitamin D deficiency
‣ Start date: 05/11/2021
‣ Action Taken: Dose not changed

ALLOPURINOL

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 100 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral

- Indication: Gout
- Start date: 05/11/2021
- Action Taken: Dose not changed

AMITRIPTYLINE

- Drug Characterisation: Concomitant
- Drug Dosage: 10 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Neuropathic pain
- Start date: 04/11/2021
- Action Taken: Dose not changed

ASPIRIN

- Drug Characterisation: Concomitant
- Drug Dosage: 75 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Cardiovascular disorder
- Start date: 05/11/2021
- Action Taken: Dose not changed

ATORVASTATIN

- Drug Characterisation: Concomitant
- Drug Dosage: 20 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Cardiovascular disorder
- Start date: 04/11/2021
- End date: 05/11/2021
- Action Taken: Dose not changed

BUPRENORPHINE

- Drug Characterisation: Concomitant
- Drug Dosage: 20 µg microgram(s)
- Drug Dosage Interval: 96 Hours
- Form: Cutaneous patch
- Route of Administration: Cutaneous
- Indication: Pain
- Start date: 05/11/2021
- Action Taken: Dose not changed

DEXAMETHASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 6 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: COVID-19
- Start date: 05/11/2021
- Action Taken: Dose not changed

ENOXAPARIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	20 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Solution for injection
‣ Route of Administration:	Subcutaneous
‣ Indication:	DVT prophylaxis
‣ Start date:	04/11/2021
‣ Action Taken:	Dose not changed

FUROSEMIDE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	40 Mg milligram(s)
‣ Drug Dosage Interval:	2 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Diuresis
‣ Start date:	05/11/2021
‣ Action Taken:	Dose not changed

IPRATROPIUM BROMIDE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	500 µg microgram(s)
‣ Drug Dosage Interval:	6 Hours
‣ Form:	Nebuliser solution
‣ Route of Administration:	Respiratory (inhalation)
‣ Indication:	Chronic obstructive airways disease
‣ Start date:	12/11/2021
‣ Action Taken:	Not applicable

PARACETAMOL

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	1 G gram(s)
‣ Drug Dosage Interval:	6 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Pain
‣ Start date:	05/11/2021
‣ Action Taken:	Dose not changed

SALBUTAMOL

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	2.5 Mg milligram(s)
‣ Drug Dosage Interval:	6 Hours
‣ Form:	Nebuliser liquid
‣ Route of Administration:	Respiratory (inhalation)
‣ Indication:	Chronic obstructive airways disease
‣ Start date:	12/11/2021
‣ Action Taken:	Not applicable

CLARITHROMYCIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	500 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Respiratory infection
‣ Start date:	05/11/2021

‣ Action Taken: Dose not changed

OMEPRAZOLE

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 20 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Antacid therapy
‣ Start date: 05/11/2021
‣ Action Taken: Dose not changed

CO-AMOXICLAV

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 1.2 G gram(s)
‣ Drug Dosage Interval: 12 Hours
‣ Form: Infusion
‣ Route of Administration: Intravenous (not otherwise specified)
‣ Indication: Respiratory infection
‣ Start date: 05/11/2021
‣ Action Taken: Dose not changed

MOVELAT

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 1 DF dosage form
‣ Drug Dosage Interval: 4 Hours
‣ Form: Gel
‣ Route of Administration: Topical
‣ Indication: Pain
‣ Start date: 06/11/2021
‣ End date: 06/11/2021
‣ Action Taken: Not applicable

CODEINE PHOSPHATE

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 30
‣ Drug Dosage Interval: 6 Hours
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Pain
‣ Start date: 04/11/2021
‣ End date: 04/11/2021
‣ Action Taken: Not applicable

DARBEPOETIN ALFA

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 40 µg microgram(s)
‣ Drug Dosage Interval: 1 Weeks
‣ Form: Suspension for injection
‣ Route of Administration: Subcutaneous
‣ Indication: Anaemia
‣ Start date: 11/11/2021
‣ Action Taken: Dose not changed

DUAKLIR GENUAIR

‣ Drug Characterisation: Concomitant

- Drug Dosage: DF dosage form
- Drug Dosage Interval: 12 Hours
- Form: Inhalation powder
- Route of Administration: Respiratory (inhalation)
- Indication: Chronic obstructive airways disease
- Start date: 05/11/2021
- Action Taken: Dose not changed

LORAZEPAM

- Drug Characterisation: Concomitant
- Drug Dosage: 2 Mg milligram(s)
- Form: Tablet
- Route of Administration: Oral
- Indication: Agitation
- Start date: 11/11/2021
- End date: 11/11/2021
- Action Taken: Not applicable

MIDAZOLAM

- Drug Characterisation: Concomitant
- Drug Dosage: 2.5 Mg milligram(s)
- Form: Solution for injection
- Route of Administration: Subcutaneous
- Indication: Agitation
- Start date: 11/11/2021
- Action Taken: Not applicable

SODIUM BICARBONATE

- Drug Characterisation: Concomitant
- Drug Dosage: 500 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Form: Tablet
- Route of Administration: Oral
- Indication: Chronic kidney disease
- Start date: 05/11/2021
- Action Taken: Dose not changed

THIAMINE HYDROCHLORIDE

- Drug Characterisation: Concomitant
- Drug Dosage: 100 Mg milligram(s)
- Drug Dosage Interval: 8 Hours
- Form: Tablet
- Route of Administration: Oral
- Indication: Vitamin B1 deficiency
- Start date: 04/11/2021
- Action Taken: Dose not changed

TRIMBOW

- Drug Characterisation: Concomitant
- Drug Dosage: DF dosage form
- Drug Dosage Interval: 8 Hours
- Form: Inhalation powder
- Route of Administration: Respiratory (inhalation)
- Indication: Chronic obstructive airways disease
- Start date: 04/11/2021
- Action Taken: Dose not changed

BARICITINIB

▶ Drug Characterisation:	Suspect
▶ Drug Dosage:	2 Mg milligram(s)
▶ Drug Dosage Interval:	48 Hours
▶ Form:	Tablet
▶ Route of Administration:	Oral
▶ Indication:	COVID-19
▶ Start date:	10/11/2021
▶ End date:	11/11/2021
▶ Action Taken:	Drug withdrawn

KEVZARA

▶ Drug Characterisation:	Concomitant
▶ Drug Dosage:	400 Mg milligram(s)
▶ Form:	Infusion
▶ Route of Administration:	Intravenous (not otherwise specified)
▶ Indication:	COVID-19
▶ Start date:	08/11/2021
▶ Action Taken:	Not applicable

casirivimab

▶ Drug Characterisation:	Concomitant
▶ Drug Dosage:	2400 Mg milligram(s)
▶ Form:	Infusion
▶ Route of Administration:	Intravenous (not otherwise specified)
▶ Indication:	COVID-19
▶ Start date:	08/11/2021
▶ Action Taken:	Not applicable

5. Causality Assessment

BARICITINIB - Generalized tonic-clonic seizure

▶ Assessment by sponsor:	Reasonable possibility
▶ Assessment by investigator:	Reasonable possibility