

## Report Overview - GB-MHRA-ESUSAR-215840423001-00108622

## Submission Details

Submitted by: Prof Richard Haynes  
Submission date: 20/02/2021

## 1. Trial Information

Reference: RECOVERY SUSAR 007  
Trial Name: 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy

## 2. Patient Details

Patient gender: Male  
Patient age at time of the side effect: 81 Years  
Patient Identification Number: 1351252

## Transient ischaemic attack

Continuing: No

## Hypertension

Continuing: Yes

## Diverticular disease

Continuing: Yes

## Anxiety

Continuing: Yes

## 3. Suspect Reactions

## Date sponsor was made aware of the SUSAR:

18/02/2021

## Country of Origin:

United Kingdom

## Narrative:

Admitted to hospital on 5-Feb-21 with severe COVID requiring CPAP. Dexamethasone started on admission. On 6-Feb-21 recruited to RECOVERY and randomised to receive baricitinib. C-reactive protein initially fell (286 mg/L on admission to 26 mg/L on 9-Feb-21) but then later rose (151 on 17-Feb-21) with abdominal pain. CT scan showed pneumoperitoneum with sigmoid perforation, most likely at time of randomisation. Treated conservatively with

intravenous antibiotics.

#### Seriousness

- Hospitalisation

#### Acute diverticular perforation

- Reaction Outcome: Recovering
- Start date: 17/02/2021

#### Abdomen CT

- Result: Acute diverticular perforation
- Test date: 17/02/2021

### 4. Suspect Medicines

#### BARICITINIB

- Drug Characterisation: Suspect
- Drug Dosage: 4 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: COVID-19
- Start date: 06/02/2021
- End date: 15/02/2021
- Action Taken: Drug withdrawn

#### MIRTAZAPIN

- Drug Characterisation: Concomitant
- Drug Dosage: 15 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Anxiety
- Start date: 05/02/2021
- Action Taken: Not applicable

#### CLOPIDOGREL SULPHATE

- Drug Characterisation: Concomitant
- Drug Dosage: 75 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Transient ischaemic attack
- Start date: 05/02/2021
- Action Taken: Not applicable

#### ATORVASTATIN CALCIUM

- Drug Characterisation: Concomitant
- Drug Dosage: 20 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Transient ischaemic attack
- Start date: 05/02/2021

‣ Action Taken: Not applicable

#### AMLODIPIN

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 5 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Hypertension  
‣ Start date: 05/02/2021  
‣ Action Taken: Not applicable

#### 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: 05/02/2021  
‣ Action Taken: Not applicable

#### ATENOLOL

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 50 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Hypertension  
‣ Start date: 05/02/2021  
‣ Action Taken: Not applicable

#### RAMIPRIL

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 5 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Hypertension  
‣ Start date: 05/02/2021  
‣ Action Taken: Not applicable

#### OMEPRAZOL

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 20 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Prophylaxis against gastrointestinal ulcer  
‣ Start date: 05/02/2021

▸ Action Taken:

Not applicable

## 5. Causality Assessment

### BARICITINIB - Acute diverticular perforation

- |                               |                        |
|-------------------------------|------------------------|
| ▸ Assessment by sponsor:      | Reasonable possibility |
| ▸ Assessment by investigator: | Reasonable possibility |