

## Report Overview - GB-MHRA-ESUSAR-215840423001-00110755

## Submission Details

- Submitted by: Prof Richard Haynes  
▸ Submission date: 23/08/2021

## 1. Trial Information

- Reference: RECOVERY SUSAR 016  
▸ 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: 60 Years  
▸ Patient Identification Number: 1421003

## Diabetes steroid-induced

- Continuing: Yes

## Bronchiectasis

- Continuing: Yes

## Asthma

- Continuing: Yes

## 3. Suspect Reactions

Date sponsor was made aware of the SUSAR:  
20/08/2021

Country of Origin:  
United Kingdom

## Narrative:

Patient with steroid-induced diabetes mellitus usually on gliclazide. Hospitalised with severe COVID-19 requiring NIV. Randomised to empagliflozin and commenced treatment on 18/08/21. Gliclazide stopped on 18/08/21 due to hypoglycaemia. 19/08/21: Received empagliflozin. Poor nutritional intake. Blood ketones raised on check (2.6), no acidosis, empagliflozin stopped. Other causes of ketosis excluded. 20/08/21 Ketones still raised at 2.9, enteral nutrition started and commenced on variable rate insulin infusion on endocrinology team advice with resolution of ketosis a few hours later. Development of ketosis felt to be a serious event as required insulin infusion for correction. 21/08/21 Patient declined NIV and died from respiratory failure relating to underlying COVID, death not felt to be related to ketosis by local investigator and responsible clinical team.

**Seriousness**

▸ Other

**Diabetic ketosis**

▸ Reaction Outcome: Recovering  
▸ Start date: 20/08/2021

**Blood ketone body increased**

▸ Result: 2.9  
▸ Unit: mmol/L  
▸ Test date: 20/08/2021

**4. Suspect Medicines****EMPAGLIFLOZIN**

▸ Drug Characterisation: Suspect  
▸ Drug Dosage: 10 Mg milligram(s)  
▸ Drug Dosage Interval: 1 Days  
▸ Form: Tablet  
▸ Route of Administration: Oral  
▸ Indication: COVID-19  
▸ Start date: 18/08/2021  
▸ End date: 20/08/2021  
▸ Action Taken: Drug withdrawn

**INSULIN**

▸ Drug Characterisation: Concomitant  
▸ Drug Dosage Interval: 0 Minutes  
▸ Form: Infusion  
▸ Route of Administration: Intravenous (not otherwise specified)  
▸ Indication: Diabetic ketosis  
▸ Start date: 20/08/2021  
▸ Action Taken: Not applicable

**MONTELUKAST**

▸ Drug Characterisation: Concomitant  
▸ Drug Dosage: 10 Mg milligram(s)  
▸ Drug Dosage Interval: 1 Days  
▸ Form: Tablet  
▸ Route of Administration: Oral  
▸ Action Taken: Not applicable

**ASPIRIN**

▸ Drug Characterisation: Concomitant  
▸ Drug Dosage: 75 Mg milligram(s)  
▸ Drug Dosage Interval: 1 Days  
▸ Route of Administration: Oral  
▸ Action Taken: Not applicable

**FEXOFENADINE**

▸ Drug Characterisation: Concomitant  
▸ Drug Dosage: 180 Mg milligram(s)

- |                            |                |
|----------------------------|----------------|
| ‣ Drug Dosage Interval:    | 1 Days         |
| ‣ Route of Administration: | Oral           |
| ‣ Action Taken:            | Not applicable |

#### HIZENTRA

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|----------------------------|----------------|
| ‣ Drug Characterisation:   | Concomitant    |
| ‣ Drug Dosage:             | 9 G gram(s)    |
| ‣ Drug Dosage Interval:    | 1 Weeks        |
| ‣ Route of Administration: | Subcutaneous   |
| ‣ Action Taken:            | Not applicable |

#### CARBOCISTEINE

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|----------------------------|---------------------|
| ‣ Drug Characterisation:   | Concomitant         |
| ‣ Drug Dosage:             | 750 Mg milligram(s) |
| ‣ Drug Dosage Interval:    | 8 Hours             |
| ‣ Route of Administration: | Oral                |
| ‣ Action Taken:            | Not applicable      |

#### GLICLAZIDE

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|----------------------------|--------------------------|
| ‣ Drug Characterisation:   | Concomitant              |
| ‣ Drug Dosage:             | 80 Mg milligram(s)       |
| ‣ Drug Dosage Interval:    | 1 Days                   |
| ‣ Route of Administration: | Oral                     |
| ‣ Indication:              | Diabetes steroid-induced |
| ‣ End date:                | 18/08/2021               |
| ‣ Action Taken:            | Not applicable           |

#### DUORESP SPIROMAX

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|----------------------------|--------------------------|
| ‣ Drug Characterisation:   | Concomitant              |
| ‣ Drug Dosage Interval:    | 12 Hours                 |
| ‣ Route of Administration: | Respiratory (inhalation) |
| ‣ Action Taken:            | Not applicable           |

#### IVABRADINE

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|----------------------------|-------------------|
| ‣ Drug Characterisation:   | Concomitant       |
| ‣ Drug Dosage:             | 5 Mg milligram(s) |
| ‣ Drug Dosage Interval:    | 1 Days            |
| ‣ Route of Administration: | Oral              |
| ‣ Action Taken:            | Not applicable    |

#### ATORVASTATIN

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|----------------------------|--------------------|
| ‣ Drug Characterisation:   | Concomitant        |
| ‣ Drug Dosage:             | 40 Mg milligram(s) |
| ‣ Drug Dosage Interval:    | 1 Days             |
| ‣ Route of Administration: | Oral               |
| ‣ Action Taken:            | Not applicable     |

#### SALBUTAMOL

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|----------------------------|--------------------------|
| ‣ Drug Characterisation:   | Concomitant              |
| ‣ Drug Dosage:             | 2.5 Mg milligram(s)      |
| ‣ Drug Dosage Interval:    | 6 Hours                  |
| ‣ Form:                    | Nebuliser solution       |
| ‣ Route of Administration: | Respiratory (inhalation) |
| ‣ Action Taken:            | Not applicable           |

#### IPRATROPIUM

- Drug Characterisation: Concomitant
- Drug Dosage: 500 µg microgram(s)
- Drug Dosage Interval: 6 Hours
- Form: Nebuliser solution
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

#### FLUTICASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 27.5 µg microgram(s)
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

#### TICAGRELOR

- Drug Characterisation: Concomitant
- Drug Dosage: 90 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

#### LANSOPRAZOLE

- Drug Characterisation: Concomitant
- Drug Dosage: 30 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

#### CARBOMER

- Drug Characterisation: Concomitant
- Form: Eye drops
- Route of Administration: Topical
- Action Taken: Not applicable

#### SODIUM HYALURONATE

- Drug Characterisation: Concomitant
- Drug Dosage: 0.1 % percent
- Drug Dosage Interval: 12 Hours
- Form: Eye drops
- Route of Administration: Topical
- Action Taken: Not applicable

#### DEXAMETHASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 6 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

#### CYCLIZINE

- Drug Characterisation: Concomitant
- Drug Dosage: 50 Mg milligram(s)
- Drug Dosage Interval: 8 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

#### COLISTIMETHATE

- Drug Characterisation: Concomitant
- Drug Dosage: 2 Miu iu(1,000,000s)
- Drug Dosage Interval: 12 Hours
- Form: Nebuliser solution
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

#### TAZOCIN

- Drug Characterisation: Concomitant
- Drug Dosage: 4.5 G gram(s)
- Drug Dosage Interval: 8 Hours
- Route of Administration: Intravenous (not otherwise specified)
- Action Taken: Not applicable

#### METOCLOPRAMIDE

- Drug Characterisation: Concomitant
- Drug Dosage: 10 Mg milligram(s)
- Drug Dosage Interval: 8 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

#### ADCAL-D3

- Drug Characterisation: Concomitant
- Drug Dosage: 1 DF dosage form
- Drug Dosage Interval: 12 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

#### SODIUM CHLORIDE

- Drug Characterisation: Concomitant
- Drug Dosage: 0.9 % percent
- Drug Dosage Interval: 6 Hours
- Form: Nebuliser solution
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

### 5. Causality Assessment

#### EMPAGLIFLOZIN - Diabetic ketosis

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