


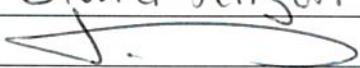
## Mawdsleys Service Summary

Trial:	REMAP-CAP Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community-Acquired Pneumonia (COVID-19)
EudraCT Number:	2015-002340-14
Products:	Ascorbic Acid (Pascorbin), 7.5g
Countries involved in study	Great Britain
Version Number:	Version 1
Date:	11 <sup>th</sup> February 2021

**Author of document:**

Name:	Samantha Howcroft
Signature:	
Date:	11/02/2021

**Quality Approval of document:**

Name:	Olivier Herrgott
Signature:	
Position:	QP
Date:	12 Feb 2021

This document is a supplement to the Summary of Product Characteristics. The purpose is to define the label text used for the labelling of the products within the trial, and services carried out by Mawdsleys.

Mawdsleys are responsible for the secondary packaging activities for the products listed above, final QP certification of IMPs for use within the Trial, import, storage, handling and distribution at:

Mawdsleys-Brooks & Company Limited  
Unit 22, Quest Park  
Wheatley Hall Road  
Doncaster  
DN2 4LT  
United Kingdom

MIA Number: UK MIA (IMP) 741  
EudraGMDP Document Reference Number: 8832

Certificate Number: UK MIA (IMP) 741 Insp GMP/GDP/IMP 741/1686685-0008  
EudraGMDP Document Reference Number: 22325

## Clinical Trials compliant labelling text

### Product packaging description

Carton containing 1 vial.

### Primary Packaging

Unblinded vial label created is Clinical Trial compliant. The text includes full requirements.

REMAP-CAP

EudraCT number: 2015-002340-14

Ascorbic Acid / Vitamin C

This box contains 1 vial of ascorbic acid 7.5g solution in 50ml vial: 150mg/ml

Sponsor: University Medical Center Utrecht

UK Coordinating centre: Imperial College London: Telephone: 07714051401

Chief Investigator: Prof Anthony Gordon

Batch Number: \*\*XXXXXX

Expiry Date: \*\*XXXXXX

Patient name:

Patient ID:

For Intravenous use only. Store at room temperature

Please refer to Administration Guide for dosage & administration.

FOR CLINICAL TRIAL USE ONLY

\*\* "XXXXXX" Indicates a variable field that will be populated accordingly at point of print.

**Secondary Packaging**

Unblinded carton label created is Clinical Trial compliant. The text includes full requirements.

REMAP-CAP

EudraCT number: 2015-002340-14

Ascorbic Acid / Vitamin C

This box contains 1 vial of ascorbic acid 7.5g solution in 50ml vial: 150mg/ml

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**Planned Expiry Extension**

The IMPD does not include a planned expiry extension.

**Revision History**

Version Number	Reason for Revision	Issue Date
1	First version	