

Study Title	PRINCIPLE
EudraCT No	2020-001209-22
Version Number, Date	V1.0 15.03.2021

Description of information needed	Label Text
Name, address and telephone number of the sponsor (the main contact for information on the product, clinical trial and emergency unblinding)	University of Oxford Joint Research Office 1st floor, Boundary Brook House Churchill Drive, Headington Oxford OX3 7GB Tel: +44 (0)1865572224 Fax: +44 (0)1865572228
Pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;	Ivermectin (3 mg) tablets The capsules are for oral administration.
Batch and/or code number to identify the contents and packaging operation;	
Trial reference code allowing identification of the <u>trial, site, investigator and sponsor</u> if not given elsewhere;	PRINCIPLE trial. University of Oxford Chief Investigator: Prof. Chris Butler
Trial subject identification number /treatment number and where relevant, the visit number;	
Kit/Pack number	
Investigator (if not included previously)	
Directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product)	Ivermectin 3mg tablets. Dosage is dependent on body weight - 45-64 kg: Take a single dose of 18mg (6 tablets) each day for three days (18 tablets in total) 65-84 kg: Take a single dose of 24 mg (8 tablets) each day for three days (24 tablets in total) ≥84 kg: Take a single dose of 30mg (10 tablets) each day for 3 days (30 tablets in total). Please return any remaining tablets to the trial team. Special instructions: You should take the daily number of tablets in one dose. The dose may be taken at any time

	of the day, but no food should be taken within two hours before or after administration.
“For clinical trial use only” or similar wording;	For clinical trial use only
Storage conditions	Store below 30°C
Period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity	3 days Expiry date: month/year Shelf life is xx.
“keep out of reach of children” except when the product is for use in trials where the product is not taken home by subjects	Keep out of reach of children