

Study Title	Principle
EudraCT No	2020-001209-22
Version Number, Date	<u>21.0</u> , 03.02.202 <u>21</u>

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Description of information needed	Label Text
Name, address and telephone number of the sponsor (the main contact for information on the product <u>and</u> 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)1865_572224 Fax: +44 (0)1865_572228
Pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;	Favipiravir (AVIGAN) <u>21</u> 00 milligram (mg) tablets. The tablets are for oral administration. <u>Nine-Five</u> tablets (2000 <u>1800</u> mg) Favipiravir to be taken <u>in the morning and four tablets to be taken in the evening (1600mg) twice a day</u> on day one, and then <u>four-two</u> tablets (800mg) twice daily for four days (<u>25</u> 0 tablets in total).
Batch and/or code number to identify the contents and packaging operation;	
Trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;	PRINCIPLE <u>T</u> rial. 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)	Day 1: <u>Nine-Five</u> tablets (1820 <u>1800</u> mg) Favipiravir to be taken <u>in the morning, and four tablets (1600mg) taken in the evening twice a day</u> Day 2-5: <u>TwoFour</u> tablets (800mg) twice daily for four days

Platform Randomised trial of Treatments in the Community for Epidemic and Pandemic Illnesses ~~Interventions~~ against COVID-19 in older peoPLE

IMP Label, Version/Date: v2.01-0 03.02.20221 EudraCT number: 2020-001209-22
Professor Christopher Butler IRAS Project number: 281958 REC No:20/SC/0158

	Special instructions: Those taking this medication must avoid excessive exposure to sunlight or artificial ultraviolet light; must not take more than 6 paracetamol in 24 hours
"For clinical trial use only " or similar wording;	For clinical trial use only
Storage conditions	Store at room temperature (1° to 30°C) and shielded from direct light
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	5 days Expiry date: month/year Shelf life: 10 years from manufacturing
" 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