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| Study Title | Principle |
| EudraCT No | 2020-001209-22 |
| Version Number, Date | 1.0, 03.02.2021 |

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| 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; | Favipiravir (AVIGAN) 200 milligram (mg) tablets. The tablets are for oral administration.  Nine tablets (1800mg) Favipiravir to be taken twice a day on day one, and then four tablets (800mg) twice daily for four days (50 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 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) | Day 1: Nine tablets (1800mg) Favipiravir to be taken twice a day  Day 2-5: Four tablets (800mg) twice daily for four days  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 |