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

|  |  |
| --- | --- |
| 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 OxfordJoint Research Office 1st floor, Boundary Brook House Churchill Drive, Headington Oxford OX3 7GBTel: +44 (0)1865572224Fax: +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 andsponsor if not given elsewhere; | PRINCIPLE trial.University of OxfordChief 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 explanatorydocument 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), inmonth/year format and in a manner that avoids any ambiguity | 5 daysExpiry date: month/yearShelf life: 10 years from manufacturing |
| “**keep out of reach of children**” except when the product is for use in trialswhere the product is not taken home by subjects | Keep out of reach of children |