**FAVIPIRAVIR (AVIGNAN Tablets 200mg)**

Thank you for taking part in the PRINCIPLE Trial. Here is some information about the trial treatment you have been given.

The medication you have been given is called **Favipiravir.** You need to take your trial medication for **5 days**. You have been given Favipiravir (**AVIGNAN)** 200 mg tablets.

**Dose and Administration**

The **Favipiravir (AVIGNAN Tablets 200mg)** 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).

For the five days you’re taking Favipiravir, you must:

Avoid excessive exposure to sunlight or artificial ultraviolet light; not take more than 6 paracetamol in 24 hours.

If you are a woman of childbearing potential or male with a partner of childbearing potential, you must use highly effective contraceptives for the 28 day duration of the trial.

If you miss a dose, take the missed dose as soon as you remember. Please skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

**Side-Effects**

Please see the Favipiravir appendix included in your participant pack, for a list of possible side-effects and what to do if you experience any of these.

**If you experience any major symptoms (side-effects) at any time after taking the study treatment, please call the 24 hour telephone line to speak to a member of the clinical team: 0800 xxxxxx.**

You will be able to tell us if you are experiencing any of these symptoms in your daily diary.

Symptom rating definitions:

|  |  |
| --- | --- |
| No problem | Symptom not experienced |
| Mild | Short-lived or mild symptoms; medication may be required. No limitation to usual activity |
| Moderate | Moderate limitation in usual activity. Medication may be required. |
| **Major** | **Considerable limitation in activity. Medication or medical attention required.**  |

This medication can cause rare allergic reactions. **If you develop any problems please stop taking**

**the medication immediately and seek clinical advice.**

**If a medical emergency related to your study treatment occurs while you are at home, you should contact 111, 999 or go to the accident and emergency (A&E) department at your local hospital.**

**Precautions:**

Please do not take the medication if you have a known allergy to Favipiravir or you are currently taking Favipiravir.

If any of these apply, please do not take the trial medication and speak to your GP and trial team.

**Storage:**

Please store the medication in a dry area, stored at room temperature (1° to 30°C/59° to 86°F), out of direct light.

Please remember that you should not be taking any other medications other than your usual prescribed medication and the medication you have been given for the trial.

If you decide that you no longer wish to take the medication, please return your medication to the trial team in the pre-paid envelope, via courier.

****