

IVERMECTIN

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 **Ivermectin**. You will need to take one dose of trial medication each day for **3 days** based on your body weight. You have been given 1 or 2 blister packs of **20 tablets, each tablet containing 3mg Ivermectin**.

Dose

The dose of Ivermectin you will be required to take each day will depend on how much you weigh:

Participant weight	Ivermectin dose	Number of 3 mg ivermectin tablets per day
45-64 kg (7.1 -10.1 st)	18 mg	6
65-84 kg (10.3 – 13.3 st)	24 mg	8
≥84 kg (≥13.3 st)	30 mg	10

Thank you for providing your weight at registration. We will confirm your weight with you during the Day 1 call so that you know how many tablets you should take each day.

Please return all unused medication in the pre-paid envelope to the trial team, via courier. We will log receipt and the number of tablets returned.

Administration

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.

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 the next day to make up the missed dose.

Side-Effects

You will be able to tell us if you are experiencing any symptoms/side-effects in your daily diary.

Please see the Ivermectin appendix included in your participant pack, for a list of possible side-effects and what to do if you experience any of these. Our clinical team will monitor symptoms of visual disturbance, confusion and seizures that you report as 'moderate', and any others that you report as 'major', whilst you are taking the drug.

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.

Symptom (side-effect) 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:

You cannot take **Ivermectin** with any of the following medication:

Quinidine, amiodarone, diltiazem, spironolactone, verapamil, clarithromycin, erythromycin, itraconazole, ketoconazole, cyclosporine, tacrolimus, sirolimus, indinavir, ritonavir, cobicistat, warfarin. You also cannot consume grapefruit juice, whilst taking Ivermectin.

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 at room temperature.

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



NUFFIELD DEPARTMENT OF
PRIMARY CARE
HEALTH SCIENCES

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PRINCIPLE

Platform Randomised Trial of Treatments in the
Community for Epidemic and Pandemic Illnesses