



Colchicine

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

The study medication you have been given is called **Colchicine**. You have been given Colchicine 500 microgram tablets.

Dose and Administration

The **Colchicine tablets** are for taking by mouth (oral administration). You should take one **Colchicine** tablet (500 micrograms) each day for 14 days.

Administration: Tablets should be swallowed whole with a glass of water.

If you are a woman 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.

If you decide that you no longer wish to take the medication, you can take your medication to your local pharmacy for disposal, when you are able to.

Side-Effects

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

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



This medication can cause rare allergic reactions. **If you develop any problems please stop taking the medication immediately and seek clinical advice.**

Should your condition worsen at any time during the trial, you should not contact the study team but contact your GP or other usual services that are open to you

Precautions:

Please do not take the medication if you have a known allergy to colchicine or any of these inactive substances: lactose, Pregelatinised Maize Starch, Stearic Acid, Purified Talc, Purified Water or Ethanol 96%.

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

- Colchicine, clarithromycin, erythromycin, ketoconazole, itraconazole, voriconazole, HIV protease inhibitors (e.g. ritonavir, atazanavir), cobicistat, verapamil, diltiazem, cyclosporin, quinidine, disulfiram.
- Please do not consume grapefruit juice whilst taking the medication.

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

Storage:

Please store at room temperature in the original package in order to protect from light.

We will ask you to record how many tablets you have remaining each day in your daily diary.

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