This Information is in addition to the formal Information Sheet required for a research project. The purpose of this sheet is to given people safety information and reassurance concerning the substance or device being tested. This approach is most commonly used for testing of drugs, and dietary or herbal supplements / remedies. This sheet may also be modified for projects which involve testing some kinds of equipment or ingestible devices.

This sheet needs to be carefully written and edited suitably for each project.

Two models are provided as a starting point only. Aim for a clear, plain English, document preferably no more than 2 sides of one sheet of paper.

**[Name of Substance] Information & Safety Sheet**

*Please be aware that you will be randomly allocated into either a XXX or placebo / control group. As a result you may not be taking XXX and neither you nor the researcher will be aware of which group you have been allocated into.*

**About [name of substance (provide scientific and common names) / device]**

XXX is the principal compound found in YYY. This compound is widely consumed / used in NNN countries and has a large variety of uses including UUU, and is used by some as a folk medicine for the treatment of III. In Australia, XXX or YYY is commonly known as NNN and is used for UUU.

**Directions for Use**

Take [specify quantity e.g. one capsule] [specify frequency e.g. twice daily] with [specify whether with / without water / juice / food]. Capsules can be taken with or without food and one capsule should be taken in the morning and one capsule in the evening (typically with breakfast and dinner).

**What to Do If You Forget to Take a dose**

If you miss a dose, take it as soon as you realise this has occurred. If you only become aware that you have missed a dose when it is time to take your next capsule, then you can take both capsules at the same time. However, you should not take more than two capsules at any one time and no more than three capsules in a [24-hour] period.

**Capsule Supply and Capsule Container**

You will initially be provided with a 4-week supply of capsules (60 capsules) and a 7-day capsule container. This container has 7 compartments labelled for each day of the week to help remind you to take the capsules and to keep track of what you have taken. It is recommended that you place two capsules in each compartment and refill the container when appropriate.

After approximately [insert time frame] [name of researcher] will contact you to find out … [e.g. how many capsules you have remaining]. If you have missed any, we ask that you be honest about this. People do forget to take capsules and it is important that we have reliable information about your capsule intake so that we can confidently assess the effects of XXX. You will be sent your second 4-week supply of capsules at this time.

**Potential Side Effects from XXX**

Studies show that XXX is safe and well tolerated by the vast majority of users. It is regularly ingested as the YYY (e.g., in NNN) and is commonly used in UUU. However, some studies have shown that mild side effects can occur in a very small portion of people (usually with intake of around to X grams a day. You will be taking only Z grams a day). These side effects usually are [list them here] and include [list specific impacts]. EITHER No studies have reported any serious side effects from its intake, although this cannot be totally ruled out. OR Rarely, (serious) side effects have been reported and can include VVV the known incidence rate is …. As a result it is important that we keep track of any side effects you may experience, whether you believe they are related to XXX intake or not.

**Evaluation of Side Effects Questionnaire**

At weeks Z and Z you will be asked to complete a questionnaire about any side effects you may have experienced resulting from you intake of XXX. You will also be asked to record any illnesses or injuries you may have experienced during this time (even if this is unrelated to your supplement intake). You will receive this questionnaire whether you are in the trial or the placebo group.

**What to do if You Experience Any Significant Side Effects or Illnesses/ Injuries**

Obviously, if you experience any significant ill-effects (whether you believe they are related to the supplements or not) seek immediate medical attention immediately. Take the Information Letter and this sheet to your appointment to provide your doctor with information about this trial.

If you experience any illness, injuries or side effects from taking your XXX, please also contact [name of researcher] immediately. You may be asked to cease participating in the study and to seek medical advice.

**If you have any questions or are experiencing any significant side effect please contact**

**[complete researcher contact details here, including an afterhours contact if necessary]**

**[Name of Substance] Information & Safety Sheet**

[include both scientific and common names]

NB, when providing participants with safety information on a common drug or substance, ensure that all the issues specified in the leaflet provided by the manufacturer are included or summarised on the information sheet. Provide participants with further information if needed.

**How does it work?**

[name of medication] contains the active ingredient \*\*\*, which is a type of \*\*\* medicine commonly called \*\*\* or belonging to the family of \*\*\* drugs.

[name of medication] is a medicine normally used to relieve \*\*\* or for \*\*\* [e.g. mild to moderate pain and inflammation]. This medication is usually available over the counter OR by prescription only.

[name of medication] works by [provide here a plain English description about how / why the medication works e.g. it impacts on \*\*\* by \*\*\* e.g. it blocks the action of a substance in the body called \*\*\*. \*\*\* is involved in the production of various chemicals in the body, some of which are known as \*\*\*, which the body produces in response to \*\*\* (such as injury and certain diseases and conditions, which can cause \*\*\*. [name of medication] blocks the production of \*\*\* these \*\*\* and is therefore effective at \*\*\*.

**What is it used for?**

[name of medication] can be used for the following conditions:

**Not to be used in:**



**Use with caution in:**

**Side effects**

The following are some of the side effects that are known to be associated with this medicine. Because a side effect is stated here, it does not mean that all people using this medicine will experience that or any side effect.

**If you have any questions or are experiencing side effects please contact**

**[complete researcher contact details here, including an afterhours contact if necessary]**