

## Procedures/Risks: Investigational Drug/Device (general)

The medication [device] that is being researched in this study is investigational. This means that the medication [device] has not been approved for marketed use by the United States Food & Drug Administration, but has been approved for research use in humans [to see if it is helpful and safe for use for the treatment of [name of condition]].

Any side effects or change in medical condition you have should be reported to the study doctor or nurse. During the study, if you need to take any new medication(s) or have any change in any of your current medicine, then you should report this to the study doctor or nurse. Be sure to be truthful with the study doctor and staff regarding your medical history, how you feel, and any medications you are taking- this is for your own safety.

Only you can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

The study medication is for *your use only*. You are cautioned to keep this study medication out of the reach of children and people who cannot read and understand written directions. The use of this study medication by persons who have *not* been authorized to use it could be dangerous.

The medication dispensed during this study is *for use by research participants only*. You are cautioned to keep this medication out of the reach of children or people who have trouble reading or understanding written directions. Use of the study medication by persons who have not been carefully screened could be [very] dangerous. You are to return all unused study medication and empty medicine containers to the study center at each visit.

The drug [device] used in this study may have side effects, some of which are listed below; some of which are unknown at this time. Please note that the list does not include all the side effects seen with this drug [device]. This list includes the more serious or common side effects with a known, or possible relationship to the study drug [device]. If you have questions concerning additional side effects of the study drug [device], please ask either the study doctor or nurse.

There can be a risk of serious and/or life threatening side effects when non-study medications when used in combination with the [study drug, device, intervention]. For your safety, you are to tell the study doctor or nurse about all medications, including vitamins and herbal supplements, that you are taking. Do this *before you start the study* and also *before starting any new medications while on the study*. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.