

## Appendix E. Participant Drug Information Sheet (67.5 mg)

### Study Medication Pack/Storage:

- Open one capsule bubble at a time.
- Use one complete blister card before opening bubbles in another.
- For each card, record the date of your first dose (from that card) on the label
- DO NOT DISCARD EMPTY CARDS. You will need to return all of your drug blister cards (empty, full and partially-used) at each clinic visit.
- Keep all unopened blister cards in the refrigerator.
- If possible, keep the open blister card in the refrigerator. Short-term room temperature storage is acceptable, but please avoid extreme temperatures (such as being left in a car on a hot day).

### Dosing:

- Take one capsule daily. (It is best to take it at the same time each day, but it's okay to vary the time)
- It can be taken with or without food.
  - If possible, swallow the capsule whole.
  - For a child who can't swallow capsules, open the capsule and mix the contents in a spoonful of something you know your child will eat, such as applesauce, pudding, or yogurt. [Do not mix it into a larger quantity of food, like a full glass of juice or bowl of yogurt, in case your child does not finish it all.]
- Record any missed doses, so you can report these dates when you return to clinic. You may use the ***TN20 Immune Effects of Oral Insulin Pill Compliance Calendar*** to help you keep track of missed doses.
- If you forget to take a capsule in the morning, take it before lunch or dinner or at bedtime.
- If you miss a whole day, take just one capsule the next day, as usual. Do not try to 'catch up' by taking two doses the next day.

### Follow-Up:

- If you (or your child, if he/she is the subject) experience any **serious health problems**, seek care immediately. As soon as you are able, please notify:
  - Study Coordinator **Insert Study Coordinator Name** at **(###)-###-####**
  - Study Doctor **Insert Study PI Name, MD** at **(###)-###-####**
- Record all illnesses and injuries that you (or your child) experiences. Note the start date, severity, and stop date. You are welcome to report these to Study Coordinator when they occur, so that you do not need to keep a written record.
- Record all medications that you (or your child) take. Note the start date, dose, frequency, and stop date, and reason for taking the medication.



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- If you have a question or concern, please contact the Study Coordinator, **Insert Study Coordinator Name**, at **(###) ### ####**.

**Missed Doses:**

Date: \_\_\_\_\_ Reason: \_\_\_\_\_

Date: \_\_\_\_\_ Reason: \_\_\_\_\_

Date: \_\_\_\_\_ Reason: \_\_\_\_\_

**NEXT VISIT WINDOW:** \_\_\_\_\_