





Rivaroxaban Xarelto®
THIS is a STUDY DRUG in children

How To Store/Reconstitute (Mix) And Give The Study Drug

Bottles containing rivaroxaban granules	100 mL syringes	Connection adapters	Dosing pipettes
			

Administration

Rivaroxaban should be given during or within 30 min after a meal.

- Use the dosing pipette provided by the study team to administer drug—it is a special syringe that can only be drawn up to the specific dose required.
- To set the right dose on a dosing pipette, pull the plunger up to the prescribed dose (1.4 mL), and lock that dose in by pressing the red button down.
- Once the button is pressed, the set dose cannot be changed.
- Clean the pipette by rinsing a couple of times with water after each use.
- Dosing pipettes can be used up to 14 days, after which a new one should be set up and used.

What If I Vomit or Miss a Dose?

If your child vomits **within 30 minutes** of the dose, give another dose. If it has been **longer than 30 minutes**, do not give another dose

If you miss a morning dose take it as soon as you remember. However, if when you remember **it is less than 5 hours before the next dose**, the missed dose should not be given anymore.

How Should the medication be stored?

- One months' supply of study drug is provided at a time.
- Keep it in the **bright blue bag**.
- Store the study drug (both granules and liquid suspension) below 25°C (either room temperature or in fridge-- DO NOT FREEZE).
- Once reconstituted, the liquid suspension can be used for up to 14 days, after which a new bottle should be used.

How do I Reconstitute or mix it?

1. Add granules to 100 mL of water (you can use the 100 mL syringes provided).
2. Insert the connection adapter into the bottle opening.
3. Shake gently for at least 60 seconds, until all granules are mixed and there are no clumps or sediment.

****PLEASE DO NOT THROW ANY MATERIALS OUT. KEEP ALL MATERIALS (USED, UNUSED, AND PARTIALLY USED) IN BLUE BAG, INCLUDING DOSING PIPETTES AND SYRINGES****

Do I need Blood work? Laboratory blood monitoring is not necessary except for study bloodwork.

MANAGING BLEEDING

1. Do not give medication
2. Apply pressure to the bleeding site if possible.
3. Consult KIDCLOT urgently. 780-407-8822 Page KIDCLOT

Study contacts: Cheri Robert (780-248-5611, 780-231-4350) or Page KIDCLOT if urgent

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