FAQ on the posology and method of administration of Ronapreve

1. **Ronapreve for treatment* of COVID-19 in adults and adolescents aged 12 years and older and weighing at least 40 kg, who do not require supplemental oxygen therapy and at increased risk of progression to severe forms of COVID-19**

* Italy does not currently provide for the use of Ronapreve for COVID-19 prophylaxis

What is the recommended dose?

The recommended dose is 600 mg of casirivimab and 600 mg of imdevimab.

How is the recommended dose prepared?

To obtain the total volume of the dose (10 mL), you should withdraw:

- 2.5 mL of casirivimab from each of the two 300 mg (120 mg/mL) disposable vials
- 2.5 mL of imdevimab from each of the two 300 mg (120 mg/mL) disposable vials

How is it administered?

In all cases, the administration of casirivimab and imdevimab must be carried out within 7 days of the onset of COVID-19 symptoms.

Intravenous route

The two monoclonal antibodies casirivimab and imdevimab should be administered together in a single intravenous infusion using a single 50-250 mL pre-filled infusion bag, containing 0.9% sodium chloride or 5% dextrose, for concomitant administration.

The infusion should be administered over 20-30 minutes. The infusion rate can be slowed down or the infusion can be suspended or stopped permanently if the patient develops any signs of infusion-related events or other adverse reactions.

At the end of the infusion, flush with 0.9% sodium chloride for injections.

Subcutaneous route

The two monoclonal antibodies casirivimab and imdevimab must be administered consecutively by separate subcutaneous injections in distinct body sites (in the upper region of the thighs, in the upper outer part of the arms or in the abdomen, avoiding the 5 cm around the navel and the waist).

Only use the subcutaneous route of administration if intravenous administration is not feasible and results in a delay in treatment.

2. **Ronapreve for treatment of COVID-19 in adults and adolescents aged 12 years and over hospitalised for COVID-19, also on conventional oxygen therapy (not high-flow and not mechanically ventilated), but with negative serology for SARS-CoV-2 anti-Spike IgG antibodies**

(according to Resolution no. 1414 of 25 November 2021 published in the Official Gazette of 26 November 2021, no. 282)

What is the recommended dose?

The recommended dose is 1200 mg of casirivimab and 1200 mg of imdevimab.

To obtain the total volume of the dose (20 mL), you should withdraw:

- 10 mL of casirivimab from the multidose 1332 mg (120 mg/mL) vial OR 2.5mL from 4 disposable 300 mg (120 mg/mL) vials
- 10 mL of indevimab from the multidose 1332 mg (120 mg/mL) vial OR 2.5mL from 4 disposable 300 mg (120 mg/mL) vials

to be injected into a single pre-filled intravenous infusion bag containing 0.9% sodium chloride or 5% dextrose, for concomitant administration according to the instructions summarized in the table below.

Infusion bag size containing	Maximum infusion rate	Minimum infusion time

0.9% sodium chloride		
50 mL	210 mL/hour	20 minutes
100 mL	360 mL/hour	20 minutes
150 mL	510 mL/hour	20 minutes
250 mL	540 mL/hour	30 minutes

The infusion rate can be slowed down or the infusion can be suspended or stopped permanently if the patient develops any signs of infusion-related events or other adverse reactions. At the end of the infusion, flush with 0.9% sodium chloride for injections.