

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. **2021-22**3 '0 2 SEP 2021

TO:

THE GENERAL PUBLIC

SUBJECT: LIST OF DRUG PRODUCTS UNDER EMERGENCY USE (DEU)

Under FDA Circular 2021-008 or the *Updated Guidelines for the Registration of Drug Products Under Emergency Use (DEU) for COVID-19*, licensed drug establishments intending to manufacture and import/ distribute drug products listed in the Philippine COVID-19 Living Recommendations may register as DEU provided that such drug products have a positive recommendation and a registered counterpart with the FDA at the time of the application.

As of 2 September 2021, the following products may be registered as Drug Products under Emergency Use (DEU) for COVID-19:

Generic Name	Strength	Dosage Form
Tocilizumab	400 mg/ 20 mL	Concentrate Solution for Infusion (IV)
	80 mg/ 4 mL (20 mg/mL)	Concentrate Solution for Infusion (IV)
	200 mg/ 10 mL	Concentrate Solution for Infusion (IV)
D 1 1/1 11	2 mg	Tablet
Baricitinib	4 mg	Tablet
Dexamethasone (as sodium phosphate)	4 mg/mL	Solution for Injection (IM/IV)
	50 mg/mL	Solution for Injection (IM/IV)
	4 mg/mL (8 mg/ 2 mL)	Solution for Injection (IM/IV)
	5 mg/ mL	Solution for Injection (IM/IV)
	2 mg/mL	Solution for Injection (IM/IV)
Heparin Sodium	5,000 IU/ mL (25,000 IU/ 5mL)	Solution for Injection (IV/SC)
	1,000 IU/ mL (5,000 IU/ 5mL)	Solution for Injection (IV/SC)
	1000 IU/ mL	Solution for Injection (IV/SC)
	5000 IU/mL	Solution for Injection (IV/SC)



Enoxaparin Sodium	60mg/0.6mL	Solution For Injection (SC)
	40 mg/0.4 mL	Solution for Injection (SC)
	4,000 IU Anti-Factor Xa	Solution for Injection
	(equivalent to 40mg) / 0.4mL	(IV/SC)
	2,000 IU Anti-Factor Xa	Solution for Injection
	(equivalent to 20mg) / 0.2mL	(IV/SC)
	6,000 IU Anti-Factor Xa	Solution for Injection
	(equivalent to 60mg) / 0.6mL	(IV/SC)
	20mg/ 0.2mL	Solution for Injection (IV/SC)
Bivalirudin	250 mg	Lyophilized Powder for Injection (I.V.)
Tinzaparin sodium	10000 anti-Xa IU/mL	Solution For Injection (SC)
Dalteparin Sodium	2500 I.U/0.2 mL Solution	Solution For Injection In Pre-Filled Syringe

For the information and guidance of all.

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