PHARMACY BULLETIN

Pharmacy Department,
Hospital Canselor Tuanku Muhriz

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JKTU MEETING RESULT (1/2021)

Newly Approved Drugs in HCTM Formulary

DRUGS	APIXABAN 2.5MG & 5MG TABLET	PEGYLATED L-ASPARAGINASE INJECTION 3750IU/5ML	MIRABEGRON 50MG PROLONGED-RELEASE TABLET
			
INDICATION & DOSE	**Indication:** Pulmonary Embolism (PE) **Dose:** 10mg twice daily for the first 7 days then 5mg twice daily for 6 months	**Indication:** Acute Lymphobastic Leukaemia and Lymphoma **Dose:** IM/IV 2,500 IU/m2 per cycle (for 3 cycles)	**Indication:** Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome. **Dose:** 25mg once daily, may be increased to 50mg once daily
HCTM APPROVED POLICY	A* Respiratory specialists only (Total patients prescribed with Rivaroxaban and Apixaban = 30 patients/year only)	A* Paediatric Oncologists and Hematologists only (40 patients/year only)	A* Urologists only (50 patients/year only) Detrusitol 4mg ER removed from HCTM Formulary (Detrusitol 2mg remains in HCTM formulary).

Newly Added Indication

SIROLIMUS 1MG TABLET

EXISTING INDICATION

A* Nephrologists (10 patients/year) (SF: RM 50/month)

Indication:

1. Renal transplant patients with acute rejection
2. Immunosuppressive agent in patients with severe systemic lupus erythematosus

A* Paediatric Surgeons and Otolaryngologists (4 patients/year)

Indication:

1. Vascular anomaly resistant to standard treatment

ADD ON INDICATION

Add on Prescriber:

A* Paediatric Nephrologists (3 patients/year) (SF: RM 50/month)

New Indication:

1. Tuberous Sclerosis Complex

DATE OF APPROVAL: 31 MAC 2021

WHAT IS COMIRNATY?

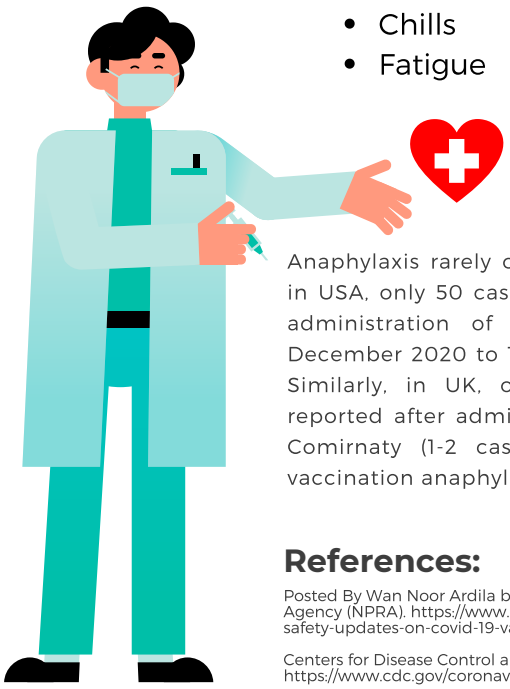
Comirnaty is among the first mRNA vaccines authorized for Covid-19 vaccination in human. Unlike other conventional vaccines, the vaccine triggers host cells that make proteins to initiate an immune response and subsequently contributes protection against SARS-CoV-2, the virus that causes Covid-19. In January 2021, Comirnaty has been approved to be used in individuals 18 years of age and older in Malaysia. Clinical trials results has shown that Comirnaty vaccine was 95% effective at preventing Covid-19 in people without evidence of previous infection.

SIDE EFFECTS OF COMIRNATY

You may experience some side effects after vaccination, which are normal signs that your body is building protection. Most of the side effects are mild to moderate and have lasted no longer than a few days. Side effects after second dose may be more intense than the ones after first dose. Upon vaccination, you will be requested to stay for 15–30 minutes at the vaccination site so that health workers are available in case of any immediate reactions or anaphylaxis.

Common side effects:

- Pain, redness, swelling at injection site
- Fever
- Headache
- Chills
- Fatigue
- Nausea
- Vomiting
- Dlarrhea
- Myalgia (muscle pain)
- Arthralgia (joint pain)



Rare, serious side effect:
Anaphylaxis

Anaphylaxis rarely occurs after Comirnaty vaccination. In fact, in USA, only 50 cases of anaphylaxis had been detected after administration of 9,943,247 doses of Comirnaty from 14 December 2020 to 18 January 2021 (5 cases per million doses). Similarly, in UK, only 130 cases of anaphylaxis has been reported after administration of more than 7 million doses of Comirnaty (1-2 cases per 100,000 doses). No death from vaccination anaphylaxis were reported in both countries.

WHO SHOULD NOT GET VACCINATED?

If you have had an anaphylaxis or an immediate allergic reaction, even if it was not severe:

- to any ingredient in Comirnaty vaccine (such as polyethylene glycol), you should not get an mRNA Covid-19 vaccine.
- after getting the first dose of the vaccine, you should not get a second dose of either of the mRNA Covid-19 vaccines.

You may still be able to get a different type of COVID-19 vaccine (AstraZeneca, Sinovac) if you are allergic to Comirnaty.

References:

Posted By Wan Noor Ardila binti Wan Abhar. (2021, February 17). Safety Updates on COVID-19 Vaccine (Comirnaty®). National Pharmaceutical Regulatory Agency (NPRA). https://www.npra.gov.my/index.php/en/health-professionals/recent-updates/426-english/safety-alerts-main/safety-alerts-2021/1527198-safety-updates-on-covid-19-vaccine-cominarty.html.

Centers for Disease Control and Prevention. (n.d.). Pfizer-BioNTech COVID-19 Vaccine Overview and Safety. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html.

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Co-Editors

Michelle Tan Hwee Peng hptan@ppukkm.ukm.edu.my
Izyan Diyana Ibrahim izyandi@ppukm.ukm.edu.my
Nur Hafiza Saripin nurhafiza@ppukm.ukm.edu.my
Designed by: **PRP Lim Sheng Hong**
03-9145 5401/5415