Pharmacy Bulletin

Hospital Segamat

Issue 1/2021

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WHAT IS COVID-19?

COVID - 19

[(co)rona + (vi)rus + (d)isease + 20(19)]

Corona viruses (CoV) are a large family of viruses and causes illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

WHO'S AT RISK:

- People with underlying medical problems like high blood pressure, heart problems, diabetes, asthma.
- Older people

MOST COMMON SYMPTOMS:

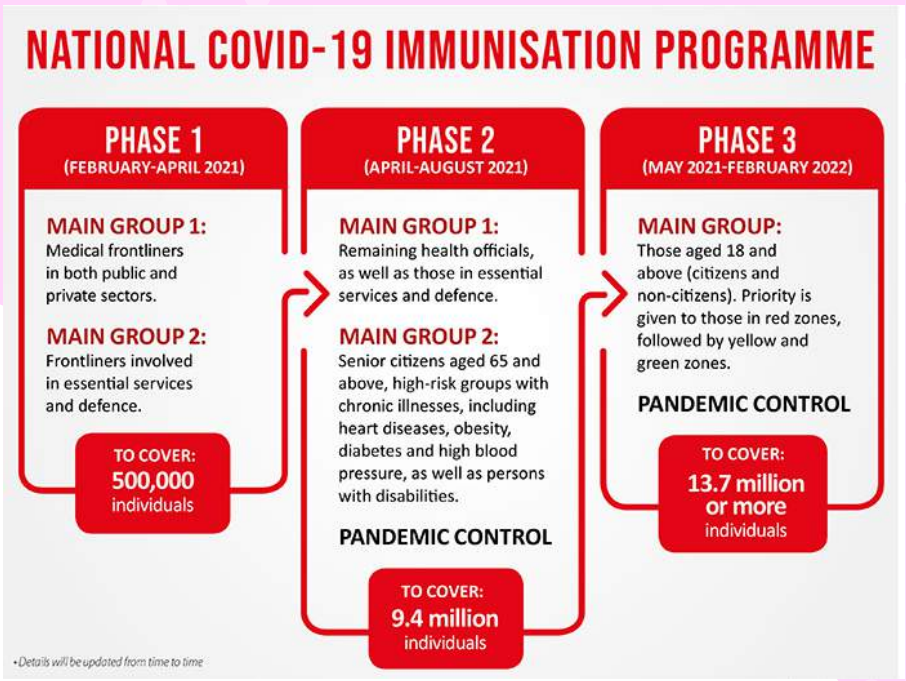
- Fever
- Shortness of Breath
- Dry cough

Some people become infected but don't develop any symptoms.

WHAT TO DO:

When you experience symptoms, seek medical attention immediately.

NATIONAL COVID-19 IMMUNISATION PROGRAMME



COVID-19 VACCINES

HOW DO THEY COMPARE?

Moderna

TECHNOLOGY: mRNA
RNA instructs our cells to produce the SARS-CoV-2 spike protein to trigger an immune response.
EFFICACY: 94.1%
CLINICAL TRIALS: Completed Phase 3. Authorized for use in USA, Canada, U.K., Israel, Switzerland, and EU.
DOSE: 2 doses, 28 days apart.
STORAGE: 30 days with refrigeration, 6 months at −20°C.

Pfizer-BioNTech

TECHNOLOGY: mRNA
RNA template for the spike protein.
EFFICACY: 95%
CLINICAL TRIALS: Completed Ph3. Authorized/approved in USA, Canada, U.K., Switzerland, Bahrain, Saudia Arabia, EU, Argentina, Chile, Costa Rica, Ecuador, Jordan, Kuwait, Mexico, Panama, and Singapore.
DOSE: 2 doses, 21 days apart.
STORAGE: Freezer storage at −70°C, 5 days with refrigeration.

Oxford-AstraZeneca

TECHNOLOGY: Viral Vector
A harmless virus is engineered to contain the gene for the SARS-CoV-2 spike protein
EFFICACY: 62% at the approved dosing scheme.
CLINICAL TRIALS: Completed Phase 3, authorized for use in U.K., Argentina, India (called CoviShield), and Mexico.
DOSE: 2 doses, 4 weeks apart.
STORAGE: refrigerated at 2–8° C.

Sinopharm

TECHNOLOGY: Inactivated Virus
SARS-CoV-2 virus is rendered inert through a chemical process that preserves the structure of the virus.
EFFICACY: Reportedly 79.34% (86% in UAE trial); unpublished data.
CLINICAL TRIALS: Phase 3 trials are ongoing; authorized/approved in China, United Arab Emirates (UAE), Bahrain, Egypt, and Jordan.
DOSE: 2 doses, 3 weeks apart.
STORAGE: refrigerated at 2–8° C.

Johnson & Johnson

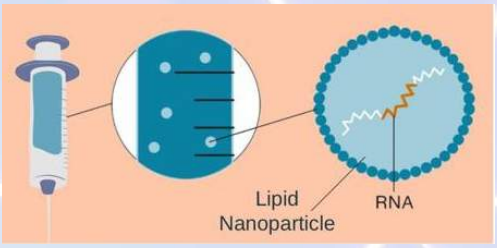
TECHNOLOGY: Viral Vector
A harmless virus is engineered to contain the gene for the SARS-CoV-2 spike protein
EFFICACY: not yet known
CLINICAL TRIALS: Completed Phase 2a, expected phase 3 trial data to be released soon.
DOSE: 1- and 2-dose schemes are being tested.
STORAGE: 2 years frozen at −20° C, 3 months refrigerated at 2–8° C.

Gamaleya

TECHNOLOGY: Viral Vector
A harmless virus is engineered to contain the gene for the SARS-CoV-2 spike protein
EFFICACY: Reportedly 91.4% (unpublished data).
CLINICAL TRIALS: Phase 3 trials are ongoing; authorized for use in Russia, Belarus, Argentina, Algeria, Bolivia, Palestine, and Serbia.
DOSE: 2 doses, 3 weeks apart.
STORAGE: Freezer storage (-20°C)

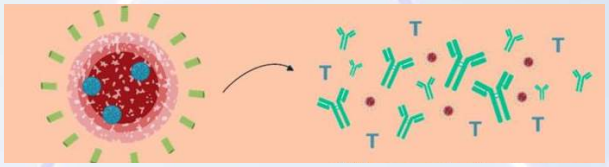
COVID-19 VACCINE
Pfizer-bioNTech (COMIRNATY)

HOW IT WORKS ?



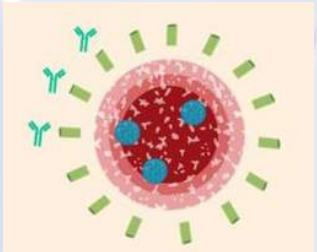
The nucleoside-modified mRNA is formulated in lipid nanoparticles

The vaccine injected into the patients



The mRNA triggers the expression of the SARS-COV-2 spike protein by the host cell

This prompts the immune system to produce antibodies and activate T-cells to destroy the infected cells.



If the patient encounters coronavirus, the antibodies and T-cells are triggered to fight the virus

PRODUCT DESCRIPTION

Active Substance

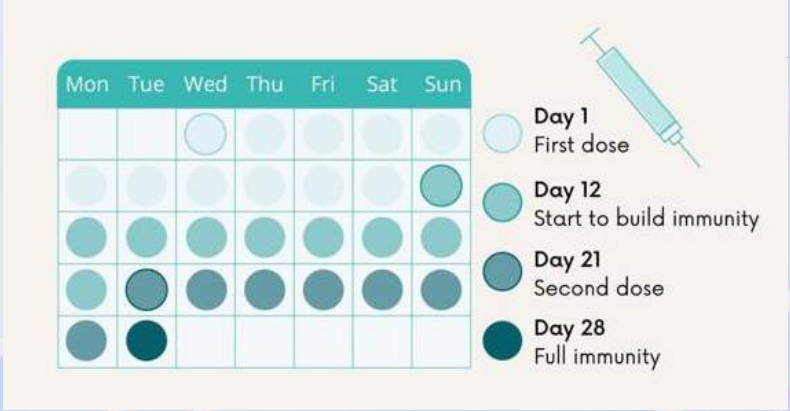
30mcg of COVID-19 mRNA vaccine embedded in lipid nanoparticles

Excipients

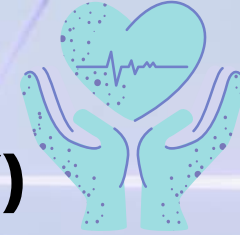
- Lipid
- Potassium Chloride
- Potassium Dihydrogen Phosphate
- Sodium Chloride
- Disodium Phosphate Dihydrate
- Sucrose
- Water for injections

VACCINATION SCHEDULE

- INTRAMUSCULAR ADMINISTRATION
- TWO DOSES
- 0.3ML PER DOSE
- FIRST AND SECOND DOSE AT LEAST 21 DAYS APART



COVID-19 VACCINE
Pfizer-bioNTech (COMIRNATY)



INDICATED FOR :

18 years old and older

CONTRAINDICATION

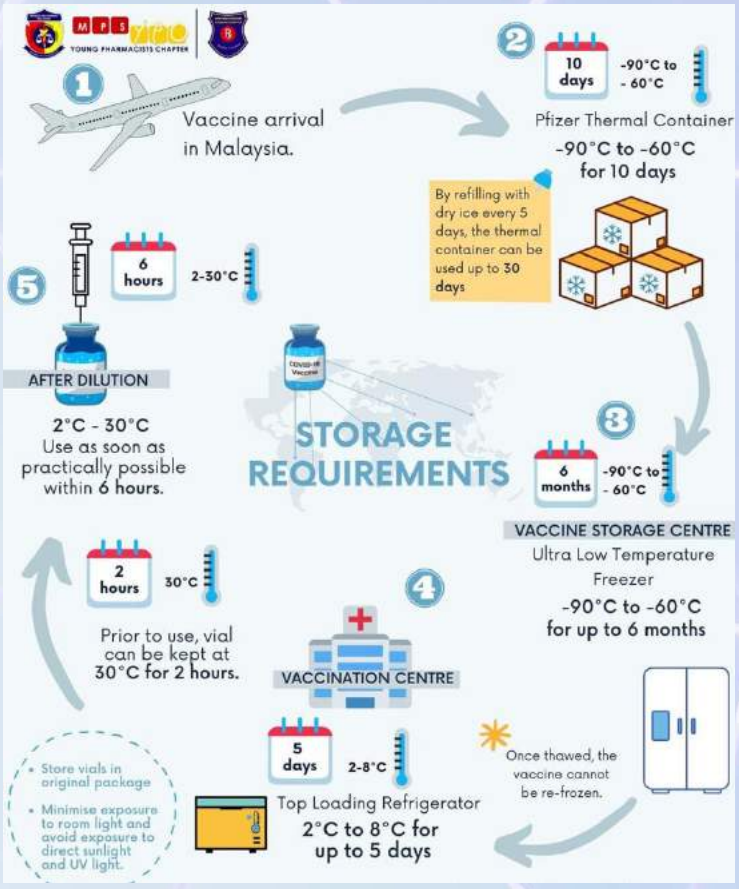
- Hypersensivity to the active substance or excipients of Comirnaty .
- History of severe allergic reaction to any vaccine or injectable therapy

COMIRNATY MUST NOT BE GIVEN TO :

- Immunocompromised individuals
- Individuals with an autoimmune disorder
- Pregnant/breastfeeding women
- Someone who had a severe allergic reaction to the first dose
- Someone who is under 18 years old

The safety and efficacy of the vaccine in the group listed have not yet established and insufficient clinical evidence to support the use of the vaccine .

STORAGE



REPORTING OF AEFI

MySejahtera Mobile Apps
(by vaccine recipents)

NPRA Official Portal
(by vaccine recipients or healthcare professionals)

Pharmacy Information System
(by healthcare professionals)

REFERENCES :

COMIRNATY PRODUCT LEAFLET .
COVID-19 IMMUNISATION PROGRAMME BOOKLET.
WHO , CORONAVIRUS DISEASE 2019 DASHBOARD.

NPRA SAFETY UPDATES

COVID-19 Vaccine (Comirnaty®)

INTRODUCTION

According to World Health Organisation (WHO), vaccination will be an important tool to stop the COVID-19 pandemic. Now, a year after the pandemic erupted, more than 60 COVID-19 vaccine candidates had been developed and some of them had been granted authorisations in hope to end the battle against this devastating pandemic soon.

Mass COVID-19 vaccination campaigns are currently underway across the globe and Comirnaty® (BNT162b2) is among the COVID-19 vaccines being deployed in those national campaigns.Unlike other conventional vaccines, Comirnaty® employs a novel genetic technology known as mRNA, which takes advantage of the process that host cells use in order to make proteins to trigger an immune response and subsequently contributes protection against SARS-CoV-2, the virus that causes COVID-19.Although Comirnaty® is among the first mRNA vaccines being authorised for human use, the technology is actually not entirely new as there was previous clinical trial of cancer vaccine using the same mRNA technology and safety had been demonstrated in the trial.

In January 2021, Comirnaty® had been granted a conditional registration in Malaysia, with indication of active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older. Comirnaty® will be integrated in the National COVID-19 Immunization Campaign which is scheduled to begin at the end of February 2021.

SAFETY DATA OF COMIRNATY® POST AUTHORISATION

Continuous and proactive safety monitoring of Comirnaty® post authorisation is utmost important to ensure that it continues to be safe for use. As more and more doses of Comirnaty® had been administered around the globe, safety data are now available for analysis to determine its safety profile in real-world settings.

In general, the current post marketing safety data for Comirnaty® is in line with the known side effects detected during clinical trials and the benefit of Comirnaty® in preventing COVID-19 infection continues to outweigh any known risks. To date, there is no new confirmed safety signal with Comirnaty®.

For instance in United Kingdom (UK), as of 31 January 2021, 20 ,319 reports have been reported for Comirnaty® with overall reporting rate around 3 to 4 reports per 1,000 doses administered. The vast majority of reports involved injection-site reactions and generalised symptoms such as headache, chills, fatigue, nausea, fever, dizziness and aching muscles. These reactions generally happen shortly after vaccination and are not associated with more serious or lasting illness.

Severe allergic reaction (anaphylaxis) and fatal outcome in frail elderly individuals were among the recent safety concerns of Comirnaty® that emerged following its widespread use. Nevertheless, experts' analysis concluded that there is no new aspect regarding the nature of severe allergic reaction and no specific safety concern has been identified for vaccine use in frail elderly individuals.

1. Severe allergic reaction (anaphylaxis)

Severe Allergic Reaction (Anaphylaxis) is a known but rare side effect of Comirnaty®. As with other vaccines, there will always be a very small proportion of susceptible individuals who might experience severe allergic reactions to the active ingredients or the excipients of the vaccine following its administration. In view of this risk, the Product Registration Holder (PRH) had advised that vaccinees to be closely observed for at least 15 minutes upon vaccination and the second dose should not be administered to those who have experienced anaphylaxis to the first dose of Comirnaty®.

In USA, 50 cases of anaphylaxis had been detected after administration of 9,943,247 doses of Comirnaty® from 14 December 2020 to 18 January 2021 (5.0 cases per million doses) and 74% of those cases occurred within 15 minutes of vaccination. A similar reporting rate was also observed in UK, where a total of 130 reports of anaphylaxis and anaphylactoid reactions had been received after more than 7 million doses of Comirnaty® had been administered (between 1 to 2 cases per 100,000 doses). No death from anaphylaxis were reported after receipt of Comirnaty® in both countries.

Comparing to USA & UK, the incidence rate of anaphylaxis post Comirnaty® administration was found to be higher in Singapore (about 2.7 cases per 100,000 doses administered). Nevertheless, the variations in the incidence rate are not alarming and to be expected, as the numbers vaccinated in Singapore during that period are relatively small. All vaccinees who experienced anaphylaxis had been promptly detected, treated, and recovered after observation or treatment.

In summary, the risk of anaphylaxis had been identified even prior to Comirnaty® authorisation and the assessment of those anaphylaxis reports to date did not identify new aspects regarding the nature of this side effect. This identified risk has also been addressed with the appropriate cautionary warning and advices (refer Product Information).

2. Risk of fatal outcome in frail elderly individuals

In January 2021, the Norwegian Medicines Agency (NOMA) had reported that there had been 23 deaths associated with Comirnaty® vaccination among severely frail elderly people in Norway. These 23 deaths occurred within six days after vaccination and the initial report by NOMA suggested that common adverse reactions to Comirnaty®, such as fever and nausea may have contributed to a more serious course and subsequent fatal outcome in those frail people.

In response to this cluster of death cases, the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 Vaccine Safety subcommittee had conducted a review based on the available information and data related to these death cases. The committee concluded that the available information did not confirm a contributory role for Comirnaty® in the reported fatal events and the reports were in line with expected all-cause mortality rates and causes of death in the sub-population of frail elderly individuals.

Similar review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), European Medicines Agency. The PRAC's assessment concluded that progression of (multiple) pre-existing diseases seemed to be a plausible cause of death for these individuals, and in some cases, palliative care had already been initiated prior to vaccination. Based on the current data, there was no new safety concern and no change regarding how Corminaty® should be used, including in frail elderly individuals.

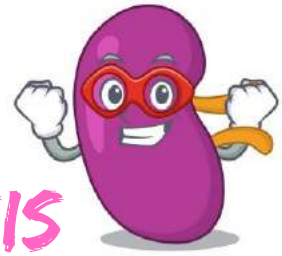
Action by NPRA

NPRA will continue to monitor the safety of Comirnaty® and other COVID-19 vaccines as they are rolled out in Malaysia.

Adapted from NPRA Safety Alerts 17 February 2021

MESALAZINE AND SULFASALAZINE

THE RISK OF NEPHROLITHIASIS



Mesalazine and sulfasalazine are anti-inflammatory agents from the 5-aminosalicylic acid (5-ASA) group which are commonly used for the treatment of inflammatory bowel disease (IBD), such as ulcerative colitis (UC) and Crohn's disease (CD). Sulfasalazine is also used to treat rheumatoid arthritis.1-4

In Malaysia, there are currently 16 registered products containing mesalazine (as tablet, granules, suppositories and enema) and three (3) registered products containing sulfasalazine (as tablet).

BACKGROUND OF THE SAFETY

Medicines Agency (EMA) regarding the risk of nephrolithiasis associated with the use of mesalazine. EMA had initiated a review after receiving reports of nephrolithiasis (kidney stones) that occurred following treatment of mesalazine. The stones were found to be composed of 100% of mesalazine deposits. Based on the data from the review, EMA requested the product registration holders of mesalazine to update the product information.

Based on a review by NPRA, the time to onset of nephrolithiasis occurred variably from one individual to another. Reported cases in literature showed that the time to onset is between several weeks to years after starting treatment.

As mesalazine is the active moiety of sulfasalazine, NPRA has extended the review to sulfasalazine products.7 There were significant reports on nephrolithiasis that were recorded in WHO database following sulfasalazine use and had also been discussed in the literature.

ADVICE FOR HEALTHCARE PROFESSIONALS

- Be alert on the risk of nephrolithiasis associated with the use of mesalazine and sulfasalazine.
- Advise patients to :

1. Consume sufficient amounts of fluids when on therapy with mesalazine or sulfasalazine.
2. Inform their doctor immediately if they experience symptoms of nephrolithiasis such as pain in the sides of abdomen and presence of blood in the urine.

- Please report all suspected adverse events associated with mesalazine and sulfasalazine-containing products to the NPRA.

ADAPTED FROM NPRA SAFETY ALERTS
29 JANUARY 2021

OSELTAMIVIR (THROMBOCYTOPENIA)

Overview

In Malaysia, oseltamivir is generally indicated for treatment and post-exposure prophylaxis of influenza infection for adults and children.Oseltamivir is an antiviral drug that acts against neuraminidase, which is the targeted catalytic site to prevent virus replication.Currently, there are 10 registered products containing oseltamivir (available as capsule and oral suspension).

Adverse Drug Reaction (ADR) Reports

To date, the NPRA has received a total of 167 reports with 280 adverse events suspected to be related to oseltamivir containing products.6 However, no ADR related to thrombocytopenia following the use of oseltamivir has been reported locally.

Background of Safety Issue

The National Regulatory Pharmaceutical Agency (NPRA) has received information from the product innovator of oseltamivir regarding thrombocytopenia associated with the use of oseltamivir. The product innovator had notified a review on this safety issue that was conducted by Swissmedic, the national regulatory agency of Switzerland. The review was initiated from the identification of four (4) case reports of thrombocytopenia following administration of oseltamivir in the Swiss national adverse drug reaction database. Following the review, product registration holder of oseltamivir was required to update the product information with this risk.

The European Medicines Agency (EMA) had also required a product information update on oseltamivir-containing products with the risk of thrombocytopenia in 2011. This request was made based on the Periodic Safety Update Report (PSUR) assessment for oseltamivir products, where there had been reports of thrombocytopenia in adults and children aged above 6 months old receiving oseltamivir.

Further review by NPRA showed that thrombocytopenia has been reported in a clinical trial and a total of 61 cases has been reported globally in the World Health Organization (WHO) database.

Advice for Healthcare Professionals:

- Be alert on the risk of thrombocytopenia associated with the use of oseltamivir.
- Monitor platelet counts for patients taking oseltamivir.
- Advise patients to inform their doctor immediately if they experience symptoms of thrombocytopenia.
- Report all suspected adverse events associated with oseltamivir-containing products to the NPRA.

Adapted from NPRA Safety Alerts
29 January 2021

CLOZAPINE

RISK OF SERIOUS BOWEL COMPLICATIONS CAUSED BY CONSTIPATION

OVERVIEW

Clozapine is an atypical antipsychotic agent which is indicated in patients with treatment-resistant schizophrenia.1 It is also indicated to reduce the risk of recurrent suicidal behaviour in patients with schizophrenia disorder. Currently, there are nine (9) products containing clozapine registered in Malaysia.

BACKGROUND OF SAFETY ISSUE

The National Pharmaceutical Regulatory Agency (NPRA) received information from United States Food and Drug Administration (US FDA) on the association of clozapine with the risk of serious bowel complications caused by constipation.Constipation is a very common and known adverse drug reaction of clozapine. However, untreated constipation may progress to serious but uncommon bowel complications, including complete bowel obstruction.In a safety review, US FDA has reviewed ten (10) local cases of constipation which lead to serious bowel problems resulting in hospitalisation, surgery and five (5) deaths. The time to onset for serious bowel events were between 3 days to 6 months after clozapine administration. The risk with clozapine is higher than with other similar agents due to its higher potency anticholinergic activity. The risk is also higher at increased doses of clozapine, and when clozapine is co-administered with other anticholinergic agents or other drugs that is known to cause constipation.Based on all available evidence, US FDA are requiring all product registration holders of clozapine containing products to update their package insert with the risk of serious bowel complications.

ADVERSE DRUG REACTION (ADR) REPORTS

The NPRA has received a total of 312 ADR reports with 534 adverse events suspected to be related to clozapine products. Adverse events related to serious bowel complications were intestinal obstruction (6), ileus paralytic (5), gastric hypomotility (3), faecaloma (2), ileus (1) and subacute intestinal obstruction (1).

ADVICE FOR HEALTHCARE PROFESSIONALS

- Be mindful on the risk of serious bowel complications when prescribing clozapine to patients.
- Assess patient's bowel function prior to clozapine initiation and avoid prescribing other anticholinergic drugs that may cause constipation.
- Advise patients to seek immediate medical attention if the patient experiences symptoms of potential bowel complications such as nausea and vomiting, bloating and abdominal distension or pain.
- Emphasize that prompt treatment is critical to prevent serious complications.
- Counsel patients and their caregivers on high fibre dietary intake and lots of fluids to prevent constipation.Monitor patients on the frequency and character of bowel movements.
- Consider prophylactic laxative treatment when starting clozapine in patients with a history of constipation or bowel obstruction.Please report all suspected adverse events associated with clozapine products to the NPRA.

Adapted from NPRA Safety Alerts
29 January 2021

Newly Approved Drugs
(Mesyuarat JKUT Bil. 1/2021)

1. POLYMYXIN B INJECTION
2. ORPHENADRINE 60MG/2ML INJECTION
3. EFAVIRENZ 200MG CAPSULE
4. BICALUTAMIDE 50 MG TABLET

Medications withdrawn From Hospital Segamat Drug Formulary
(Mesyuarat JKUT Bil. 1/2021)

1. BUDESONIDE 64 MCG NASAL SPRAY
2. CETIRIZINE HCL 10 MG TABLET
3. HYOSCINE N-BUTYLBROMIDE 1 MG/ML LIQUID
4. RITONAVIR 100 MG CAPSULE
5. PERITONEAL DIALYSIS SOLUTION (4.25% DEXTROSE)
6. SULFADOXINE 500MG & PYRIMETHAMINE 25MG TABLET (FANSIDAR®)
7. GLYCOPYRRONIUM 50MCG, INHALATION POWDER HARD CAPSULES (SEEBRI®)
8. DESMOPRESSIN 100 MCG/ML NASAL SPRAY
9. HYPROMELLOSE 0.3 %, CARBOMER 980 OPHTHALMIC GEL (GENTEAL®)

PRODUCT BRAND CHANGES (JAN - MAC 2021)

Bromhexine 8mg Tablet

Brand: Biscomin

Manufacturer: MPI

Brand: Dysolvon

Manufacturer: Dynapharm

Alendronate 70mg Tablet

Brand: Alendronate

Manufacturer: Hovid

Brand: Apo-alendronate

Manufacturer: Apotex Inc.

Telmisartan 40mg Tablet

Brand: Tolura

Manufacturer: KRKA

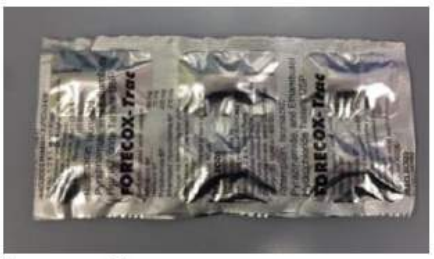
Brand: Teleact

Manufacturer: Ranbaxy

Rifampicin/Isoniazid/Pyrazinamide/Ethambutol Tablet

Brand: AKurit-4

Manufacturer: Lupin LTD



Brand: Forecox-Trac

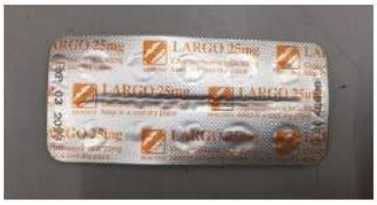
Manufacturer: Macleods

PRODUCT BRAND CHANGES (JAN - MAC 2021)

Chlorpromazine 25mg Tablet

Brand: Chlorpromazine 25

Manufacturer: Idaman Pharma



Brand: Largo 25

Manufacturer: Beacon

Sertraline 50mg Tablet

Brand: Aurasert 50

Manufacturer: Aurobindo

Brand: Sertift 50

Manufacturer: Ranbaxy

Escitalopram 10mg Tablet

Brand: Espran

Manufacturer: Torrent

Brand: Eslo-10

Manufacturer: Hetero

Frusemide 20mg/2ml Injection

Brand: Fusix

Manufacturer: SM Pharmaceuticals

Brand: Akoset

Manufacturer: Duopharma

PRODUCT BRAND CHANGES (JAN - MAC 2021)

Iron Sucrose 20mg/ml Injection

Brand: Sucrofer

Manufacturer: Baxter

Brand: Ainiron

Manufacturer: Ain Medicare

Heparin 5000IU/ml Injection

Brand: Heparinol

Manufacturer: Ain Medicare

Brand: Unihepa

Manufacturer: Duopharma

Human Albumin 20% Injection (50ml)

Brand: Human Albumin Grifols 20%

Manufacturer: Instituto Grifols

Brand: Human Albumin 20% Behring

Manufacturer: CSL Behring

Ravin Enema

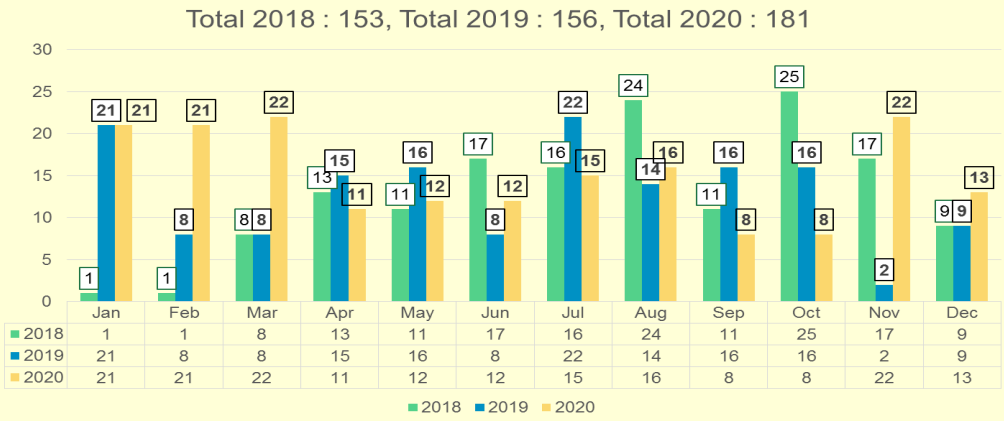
Brand: HLP Ravin Enema

Manufacturer: HLP

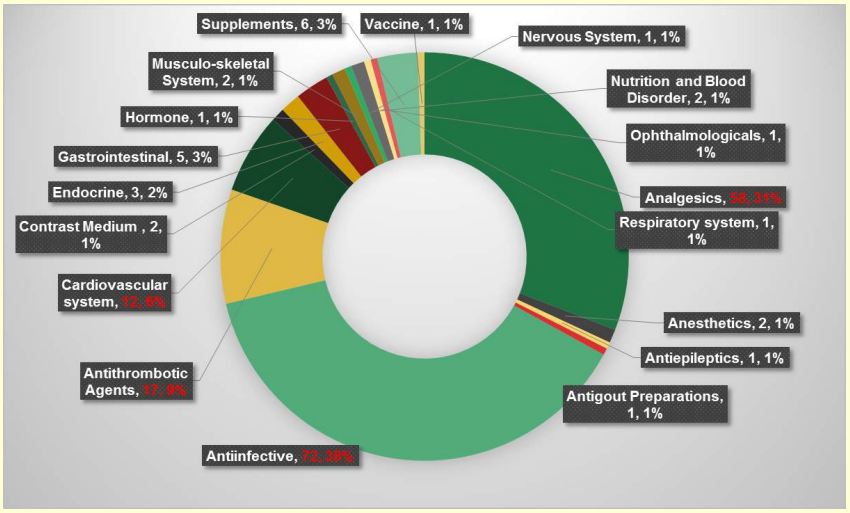
Brand: Royce Enema

Manufacturer: Royce

ADR Analysis
Hospital Segamat Year 2020



Total ADR Cases In Hospital Segamat According to Drug Group (2020)



Top 4 classes of Drugs that Contributed to ADR Cases In Hospital Segamat (2020)

Drug Class	Drugs
Antiinfectives	Cefuroxime (15), Amoxicillin & Clavulanate (11), Amoxicillin (9), Benzylpenicillin (5) Cloxacillin (5), Cephalexin (4), Ampicillin + Sulbactam (3)
Analgesics	Paracetamol (14), Diclofenac (13), Naproxen (13), Ibuprofen (3), Indo-methacin (2), Mefenamic Acid (3), Tramadol (3)
Antithrombotic Agents	Acetylsalicylic Acid (11), Clopidogrel (2), Cardiprin (2), Ticlopidine (1), Streptokinase (1)
Cardiovascular System	Amlodipine (3), Amiodarone (1), Hydrochlorothiazide (1), Diltiazem (1), Prazosin (1), Losartan/ Hydrochlorothiazide (1), Perindopril (1), Simvastatin (1), Telmisartan (1)

Name: Jabatan Farmasi	Year: 2021	Month: Jan - March	Pharmacy Activities

Program Vaksinasi Covid-19 Hospital Segamat

Program vaksinasi peringkat Hospital Segamat telah bermula pada 28 Februari 2021 yang bertempat di Dewan Perdana. Program vaksinasi ini melibatkan seramai 750 staff hospital.

Ketibaan vaksin kumpulan pertama di Hospital Segamat

Antara penerima awal vaksin Covid-19 peringkat hospital

Vaksinator yang ditugaskan untuk memberikan suntikan

Kaunseling yang dijalankan oleh pegawai farmasi

Ruang observasi selepas menerima suntikan

Name: Jabatan Farmasi	Year: 2021	Month : Jan - March	Pharmacy Activities

Majlis Perpisahan Jabatan Farmasi

Majlis perpisahan staff Jabatan Farmasi telah diadakan pada 6 Januari 2021 yang lalu. Staff yang terlibat ialah Encik Zulhilmi, Cik Ainur,Cik Miranda, Puan Zainab dan Encik Azzem. Selamat maju jaya diucapkan kupada meraka !

Bergambar kenangan bersama Ketua Pegawai Farmasi

Majlis perpisahan yang dianjurkan Unit OPD

welcome new staff

FATIN FATIHAH BINTI ZAKARIA

Penolong Pegawai Farmasi (U29)

Drug Information & Enquiries on Medication

Drug Information Centre Hospital Segamat
can be reached at 07-9433333 (ext.141)
during office hours (Mon to Thur, 8.00am to 5.00pm).