



THE

# PRESCRIPTION

Issue 2 Jul – Dec 2017



**Advisors**

Pn. Normawati Muhamad

Pn. Masitah Husin

**Editors**

Pn. Asmahani Ramelan

Pn. Low Woan Jinn

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## FDA DRUG SAFETY COMMUNICATION



The U.S. Food and Drug Administration (FDA) is alerting the public that preliminary results from a safety clinical trial show an increased risk of heart-related death with febuxostat compared to another gout medicine called allopurinol.

Health care professionals should consider this safety information when deciding

whether to prescribe or continue patients on febuxostat.

The safety trial was conducted in over 6,000 patients with gout treated with either febuxostat or allopurinol. The primary outcome was a combination of heart-related death, non-deadly heart attack, non-deadly stroke, and a condition of inadequate blood supply to the heart requiring urgent surgery. The preliminary results show that overall, febuxostat did not increase the risk of these combined events compared to allopurinol. However, when the outcomes were evaluated separately, febuxostat showed an increased risk of heart-related deaths and death from all causes.

The febuxostat drug labels already carry a *Warning and Precaution* about cardiovascular events such as heart attacks and strokes. Health care professionals and patients are urged to report any side effects involving febuxostat to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

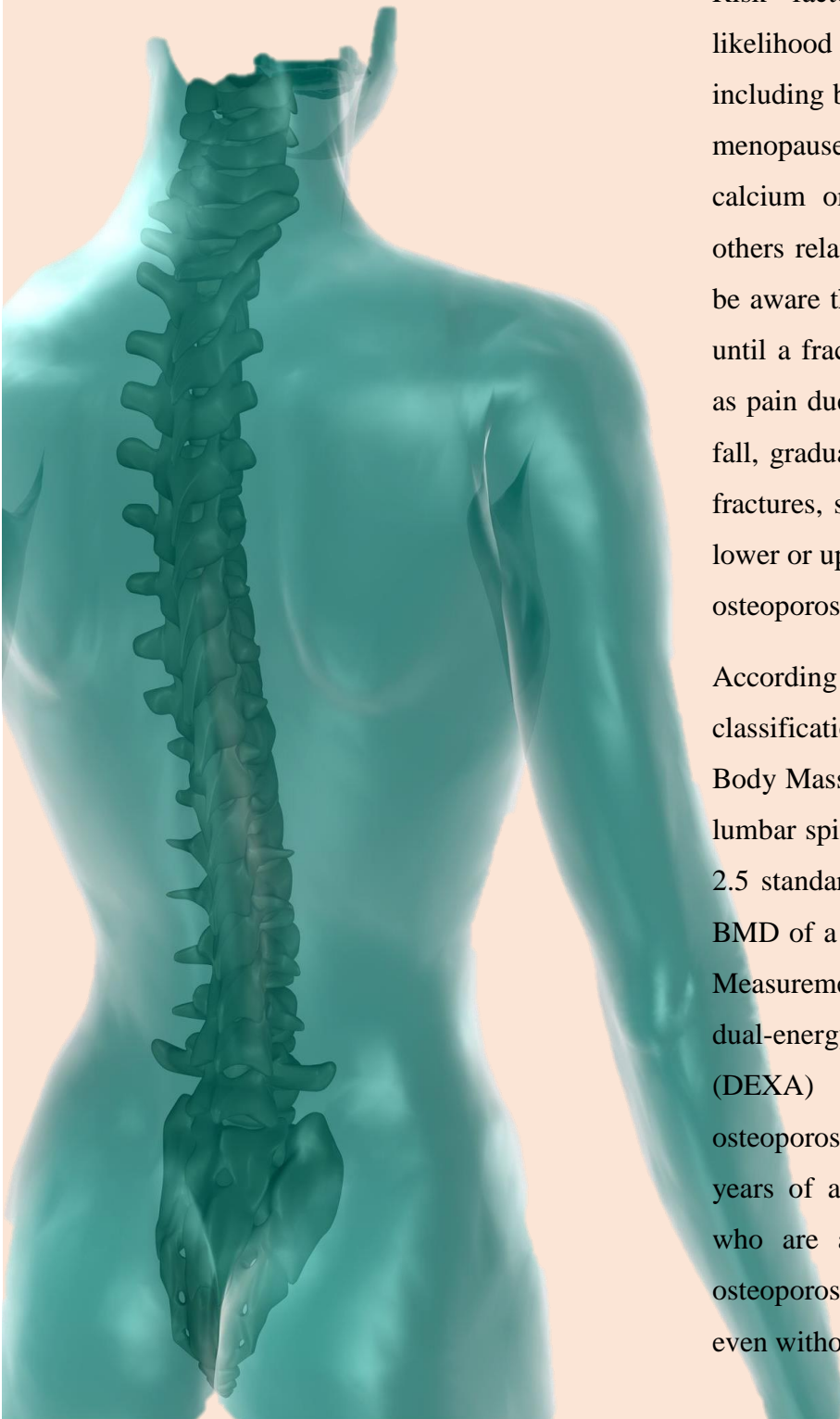
Source: <https://www.fda.gov/Drugs/DrugSafety/ucm584702.htm>

# OSTEOPOROSIS

Osteoporosis is a 'silent disease' that affects the bones.<sup>3</sup> It is characterized by low bone mass, decreasing the strength and resulting in fragile bones. As a result, the bones become more porous, gradually making them weaker, more brittle, and likely to break.<sup>3</sup>

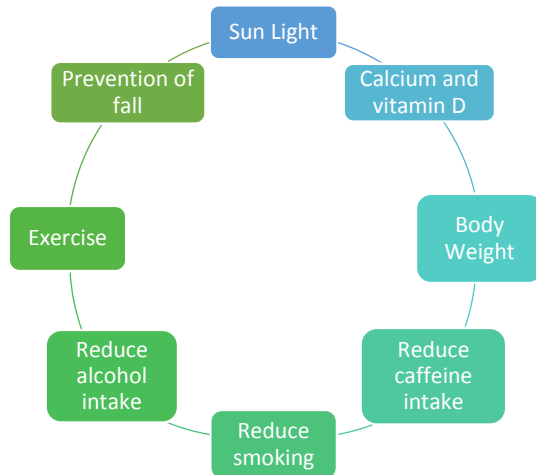
Risk factors that may increase the likelihood of developing osteoporosis including being a woman, advanced age, menopause or low levels of estrogen, low calcium or low vitamin D intake and others related.<sup>7</sup> Often, a person may not be aware that he or she has osteoporosis until a fracture occurs.<sup>7</sup> Symptoms such as pain due to fractures following minor fall, gradual loss of height due to spinal fractures, stooped posture and persistent lower or upper back pain is suggestive of osteoporosis.<sup>3</sup>

According to WHO diagnostic classification, osteoporosis is defined by Body Mass Density (BMD) at the hip or lumbar spine that is less than or equal to 2.5 standard deviations below the mean BMD of a young-adult reference range.<sup>2</sup> Measurement of hip and spine BMD with dual-energy x-ray absorptiometry (DEXA) is the gold standard for osteoporosis diagnosis.<sup>2</sup> Patients over 65 years of age with multiple risk factors who are at sufficiently high risk for osteoporosis, can be started on treatment even without BMD measurement.<sup>3</sup>



## HOW CAN OSTEOPOROSIS BE MANAGED?

### A) NON PHARMACOLOGICAL THERAPY<sup>1</sup>



### B) PHARMACOLOGICAL THERAPY

#### ANTIRESORPTIVE THERAPY

Calcium supplementation combined with Vitamin D is able to prevent secondary hyperparathyroidism and bone destruction. Vitamin D is required to maximize intestinal calcium absorption.<sup>3</sup>

Activated Vitamin D (e.g. calcitriol 0.25 µg twice daily or alfacalcidol 1 µg once daily) has been demonstrated to increase BMD in those with established osteoporosis and reduce vertebral and non-vertebral fractures. The reduction in fracture risk is in the spine and in those with mild to moderate osteoporosis.<sup>5</sup> Another form of widely available vitamin D is cholecalciferol.

The recommended daily intake for calcium is 1000 mg (both dietary and





## BISPHOSPHONATE

A bisphosphonate decreases the rate of bone resorption via actions on osteoclasts or an osteoclast precursor; leading to an indirect increase in bone mineral density.

After discontinuation, the increased BMD is sustained for prolonged period. Common adverse effect includes esophageal, gastric or duodenal irritation, ulceration or bleeding may occur when administration direction are not followed. Intravenous Bisphosphonates adverse effects include fever, flu-like symptom, and local injection site reaction. Osteonecrosis of jaw (ONJ) and subtrochanteric femoral (atypical) fractures are rare side effects seen.<sup>3</sup> Table 1 shows the summary of medication.

Drug	Prevention in postmenopausal women	Treatment in postmenopausal women and men	Glucocorticoid-induced Osteoporosis
Alendronate	5mg OD/ 35mg once Weekly	10mg OD/ 70mg once weekly	5mg OD
Risedronate	5mg OD/ 35mg once Weekly/ 150mg once monthly		5mg/day
Ibandronate	150mg once monthly 3mg IV every 3 months administer over 15-30 sec (Treatment only)	NA	NA
Zoledronic acid	Reclast- 5mg IV over > 5min every 2 years	Reclast- 5mg IV over > 15min every year	Reclast- 5mg IV over : 15min every year

Table 1: Types of commercially available biphosphonates



## MIXED ESTROGEN AGONISTS/ANTAGONISTS

Raloxifene is an estrogen agonist on bone but antagonist on breast and uterus.<sup>3</sup> It is approved for the prevention and treatment of postmenopausal osteoporosis.<sup>3</sup> After discontinuation of it, the beneficial effect is lost and bone loss returns to age.<sup>2</sup>

Raloxifene is associated with a decrease in total or LDL cholesterol, neutral effects on HDL but slight increased in triglycerides.<sup>2</sup> It has black box warning, urging caution in women at risk for stroke.<sup>4</sup> Recommended dosage is 60mg orally per day.<sup>4</sup>

### STRONTIUM RANELATE

It is indicated for the treatment of post-menopausal osteoporosis to reduce the risk of vertebral fractures. It is also used in severe osteoporosis men with increased risk of fracture due to age/ or bone mineral density (BMD) scores.<sup>3</sup> Strontium ranelate increases bone formation and decreases bone resorption and improve bone biomechanical properties such as bone strength. Headache, nausea, diarrhoea, loose stools, dermatitis, risk of myocardial infarction are adverse effect of Strontium ranelate. Method of administration include 2g of sachet per day is dissolved in water, prior to bedtime, preferably 2 hours after eating.<sup>9</sup>



### DENOSUMAB

It is a fully monoclonal antibody that binds to RANKL, blocking its ability to bind to its receptor activator of nuclear factor kappa B (RANKL) on the surface of osteoclasts.<sup>3</sup>

It inhibits osteoclast formation, function and survival.<sup>3</sup> The recommended dose is 60mg subcutaneous injection in the upper arm, upper thigh or abdomen once every 6 months.<sup>3</sup> Common adverse effect is back or musculoskeletal pain, hypercholesterolemia, cystitis, decreased serum calcium and skin reactions.<sup>8</sup>

### CALCITONIN

Calcitonin is an endogenous hormone released from the thyroid gland when serum calcium is elevated.<sup>3</sup> It is reserved as third-line agent because efficacy is less than with other antiresorptive therapies.<sup>2</sup> It is indicated for osteoporosis treatment for women at least 5 years past menopause.<sup>2</sup> Only vertebrate fractures have been documented to decrease with intranasal calcitonin.<sup>2</sup>

It does not consistently affect hip acute vertebral fractures. Calcitonin may provide pain relief to some patients with acute vertebral fractures.<sup>2</sup> If used, it should be prescribed for short-term treatment (4 weeks) and should not be used with other analgesics.<sup>2</sup> Intranasal dose: 200 units daily (1 spray), alternate nostrils daily.<sup>4</sup> SC/IM administration: 100 unit every other day with calcium (1000mg/day) and vitamin D (400 IU/day).<sup>4</sup> It is rarely used because of the adverse effects and cost.<sup>2</sup>



## ESTROGEN THERAPY (ET)

Approved by FDA for prevention of osteoporosis, but should only be used for short-term in women who need estrogen therapy for management of menopausal symptoms such as hot flushes. ET with or without progestogen significantly reduces fracture risk.<sup>3</sup>

Increase in BMD is less than biphosphonates, denosumab, or teriparatide but greater than raloxifene or calcitonin.<sup>3</sup> When ET is discontinued, bone loss accelerates and fracture protection is lost.<sup>3</sup> It is first line treatment for prevention and treatment of osteoporosis in women below 60 years.<sup>6</sup> In this group of women, ET has not been shown to increase the risk of cardiovascular events, stroke, venous thromboembolism and hemorrhagic strokes.<sup>2</sup> Initiating ET in women after 60 years for the sole purpose of prevention of osteoporotic fractures is not recommended.<sup>6</sup>

## ANABOLIC THERAPIES

Teriparatide (Forteo) is a recombinant product representing the first 34 amino acids in human parathyroid hormone (PTH). It increases bone formation, the bone remodeling rate and osteoblast number and activity.

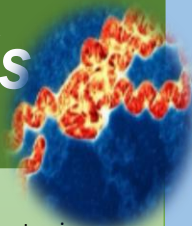
FDA approved for postmenopausal women, men and patients taking corticosteroids who are at high risk for fracture. Candidates for therapy include patients with a history of osteoporotic fracture, multiple risk factors for fracture, very low BMD (T-score <-3.5) or those who have failed or intolerant to bisphosphonate therapy. The dose should be given with the patient either lying or sitting in case of orthostatic hypotension Discontinuation of therapy results in decreased BMD, which can be alleviated with subsequent antiresorptive therapy. Dose recommended is 20mcg subcutaneously once daily in the thigh or abdominal area for up to 2 years.



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3. Clinical Practice Guideline on Management of Osteoporosis (2012), Revised in 2015
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# Leptospirosis



## WHAT IS LEPTOSPIROSIS

It is an infectious disease caused by bacteria *Leptospira*

## MODES OF TRANSMISSION

*Leptospirosis* has a very wide range of natural rodent, and non-rodent reservoir hosts especially rats, cattle, dogs, foxes, rabbits, etc.

## HOW LEPTOSPIROSIS IS SPREAD

### How Leptospirosis is spread?

People contract the disease by direct contact with contaminated water.



## TREATMENT

### Adults

- Severe cases are usually treated with high doses of IV C-penicillin (2 M units 6 hourly for 5-7 days). Less severe cases treated orally with antibiotics such as doxycycline (2 mg/kg up to 100 mg 12-hourly for 5-7 days), tetracycline, ampicillin or amoxicillin.
- Third generation cephalosporins, such as ceftriaxone and cefotaxime, and quinolone antibiotics may also be effective.
- Jarisch-Herxheimer reactions may occur after the start of antimicrobial therapy.
- Monitoring and supportive care as appropriate, e.g. dialysis, mechanical ventilation.

### Paediatrics

Preferred	Alternative	Comments
Penicillin G 100000U/ kg/ dose IV 6hourly x 7days	>8yrs: Doxycycline 4mg/kg/dose oral 12hourly x 7days	Penicillin: use in moderate to severe disease caution in impaired renal function Jarisch-Herxheimer reaction has been described in patients with leptospirosis
	<8yrs: Ampicillin 75-100mg/kg/dose oral 6hourly x 7days or Amoxicillin 50mg/kg/dose oral 6- 8hourly x 7days	Doxycycline: used for only mild disease can cause permanent discoloration of teeth  Ampicillin/ Amoxicillin: 2nd line agent or for pts < 8yrs

### Prophylaxis

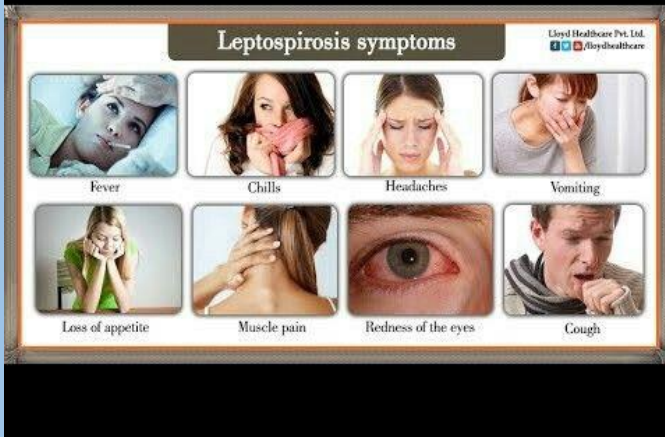
#### Preexposure Prophylaxis:

- Doxycycline 200mg stat dose then weekly throughout the stay OR
- Azithromycin 500mg stat dose then weekly throughout the stay (For pregnant women and those who are allergic to Doxycycline)

#### Empirical treatment for Post-Exposure:

- Doxycycline 200mg stat dose then followed by 100mg BD for 5 – 7 days for those symptomatic with the first onset of fever. OR
- Azithromycin 1gm on Day-1, followed by Azithromycin 500mg daily for 2 days (For pregnant women and those who are allergic to Doxycycline)

## COMMON SIGN AND SYMPTOMS



## PREVENTION

- Avoid potential source of infection such as contaminated water and soil
- Rodent control
- Protection of food from animal contamination

## REFERENCES

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2. GUIDELINES FOR THE DIAGNOSIS, MANAGEMENT, PREVENTION AND CONTROL OF LEPTOSPIROSIS IN MALAYSIA. (2011). Retrieved from [http://www.moh.gov.my/images/gallery/GarisPanduan/GL\\_Leptospirosis%202011.pdf](http://www.moh.gov.my/images/gallery/GarisPanduan/GL_Leptospirosis%202011.pdf)

# OBESITY



Obesity is defined as the accumulation of excess body fat, to an extent that it may impair health. A person's health in relation to their weight can be classified by using Body Mass Index (BMI). Another way obesity can be measured is by measuring the waist-hip ratio (WHR). This is calculated as waist measurement divided by hip measurement in centimeter. WHO states that abdominal obesity is defined as a waist-hip ratio as above 0.90 for males and above 0.85 for females.

There are many factors associated to obesity, but listed below are the most common ones.

- Genetics
- Over eating/Frequency of eating
- Physical inactivity
- Medications
- Psychological factors
- Diseases
- Social issues
- Ethnicity
- Childhood weight
- Hormones

Obesity can cause many health complications. The most common ones are :

- Type 2 diabetes
- High blood cholesterol and high triglyceride levels in the blood
- Diseases of the heart and blood vessels such as high blood pressure, atherosclerosis, stroke
- Respiratory problems such as obstructive sleep apnea, asthma
- Osteoarthritis
- Emotional health issues such as low self-esteem or depression
- Non-alcoholic fatty liver disease

Effective weight loss typically involves more than one approach, and your health care provider will determine which options are right for you. Weight loss approaches include the following:

- Dietary changes, including caloric restriction, altering proportions of certain food groups (eg, low-fat or low-carbohydrate diet plans), meal replacement therapy and structured commercial weight-loss programs
- Exercise and activity
- Prescription weight loss medication
- Weight loss surgery (Known as bariatric surgery ; RYGB, AGB, sleeve gastrectomy)

Some health care providers may prescribe medications for treating obesity in individuals with a BMI of 30 kg/m<sup>2</sup> or higher or with a BMI of 27 kg/m<sup>2</sup> or higher who have weight-related health issues or risks. Your health care provider will determine whether you are a candidate for these medications and may suggest following a well-known diet plan or visiting a nutritionist to design a dietary plan suited to your needs. Examples of common medications are, orlistat 120MG, which is taken 3 times a day with each main meal, or up to 1 hour after meal. Another type of medication that is also quite common is phentermine. There are two strengths, 15MG and 30MG, either one take once daily.

Losing weight isn't always easy, and there's no quick fix. But with motivation and dedication to adopting healthy lifestyle habits, including eating a healthy, balanced diet, following an appropriate exercise routine and managing stress, you can achieve [successful weight loss](#), take control of your health and enhance your overall quality of life.

## REFERENCES

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- <https://www.nhlbi.nih.gov/health/health-topics/topics/obe/signs>
- <http://reference.medscape.com/drug/alli-xenical-orlistat-342068>
- <http://reference.medscape.com/drug/adipex-p-lomaira-phentermine-343002>

# AKTIVITI FARMASI 2017



World Kidney Day pada 7 Mac 2017



Bengkel Asthma pada 13 Mei 2017

# AKTIVITI FARMASI 2017



Konvensyen Inovasi dan Kreativiti Farmasi 2017 pada 6-8 Ogos 2017



Pensijilan Semula Amalan 5S daripada MPC pada 17 Ogos 2017



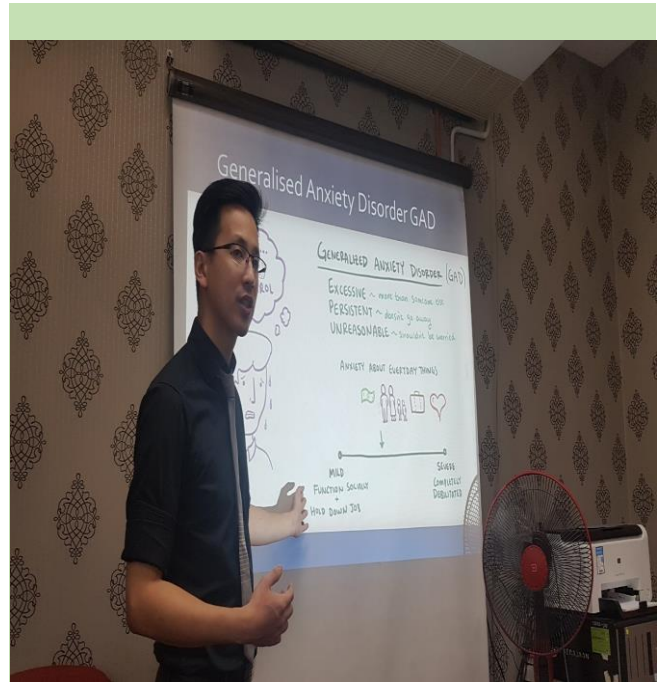
Jamuan Hari Raya



# AKTIVITI FARMASI 2017



Bengkel "Pain at a Glance" pada 11 September



Bengkel "Psychopharmacotherapy Updates" pada 20 September 2017



Program Hari Bertemu Pelanggan pada 13 September 2017



Bengkel Thalassemia pada 7 Oktober 2017

# AKTIVITI FARMASI 2017



Sambutan Hari Warga Emas dan Dietetik HTAR pada 10 Oktober 2017

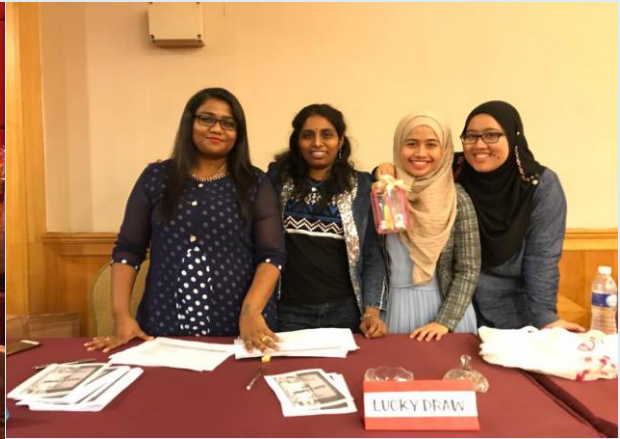


Sambutan Hari Mental Sedunia pada 10 Oktober 2017



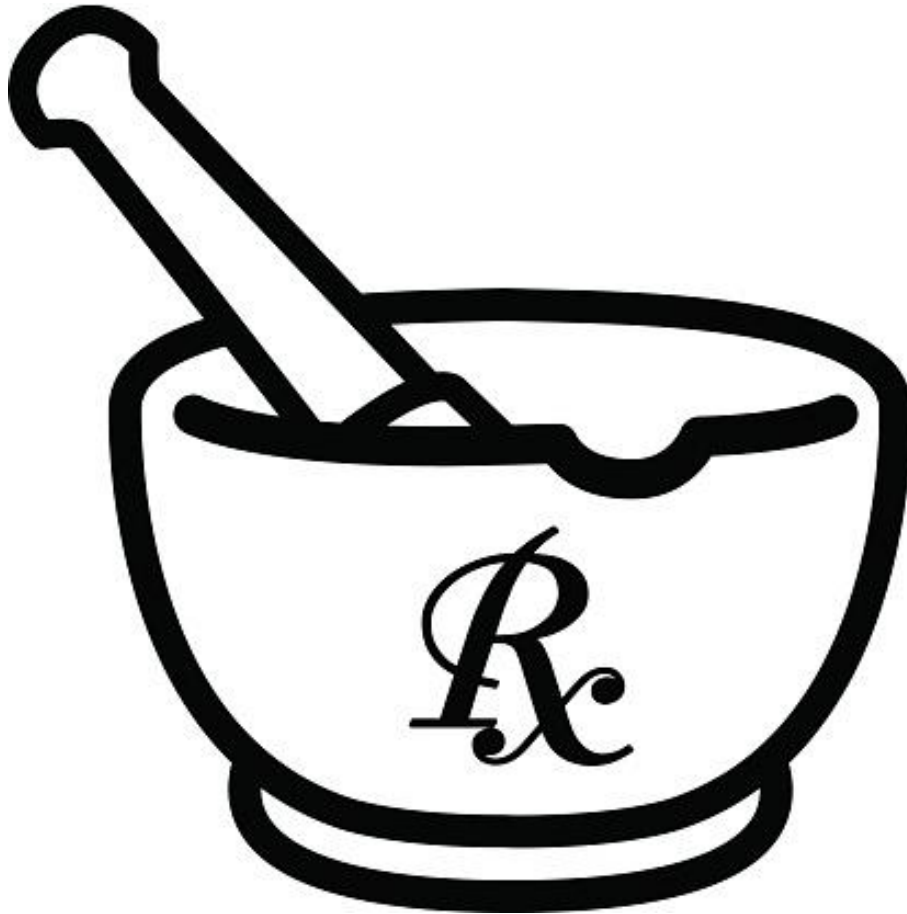
Aktiviti Sukan Sempena Hari Sukan Negara : Pertandingan Bowling Terbuka pada 14 Oktober 2017

# ★ AKTIVITI FARMASI 2017 ★



Malam Mesra Jabatan Farmasi 2017 pada 15 Oktober 2017

De Palma Hotel Shah Alam



POISON RESOURCE AND INFORMATION CENTER  
HOSPITAL TENGKU AMPUAN RAHIMAH, KLANG  
EXT 1342