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HOSPITAL KAJANG

ADVISOR

PN HASNIZAN BINTI HASAN

EDITOR

PN KHAIRUL BAR-RIAH BINTI MAT SALLEH

PN LIM LEE LING

WAN NURUL MURSYIDA

CONTRIBUTORS

HEW SIEW CHUEN

CHIN SHIN CHEE

NUR AMANINA

GOH JING YI

RAJA AINUL BASYIRAH

AISYAH AMANINA BINTI ABDULLAH

Inside Stories

Prepared By: Hew Siew Chin
& Amy Chin

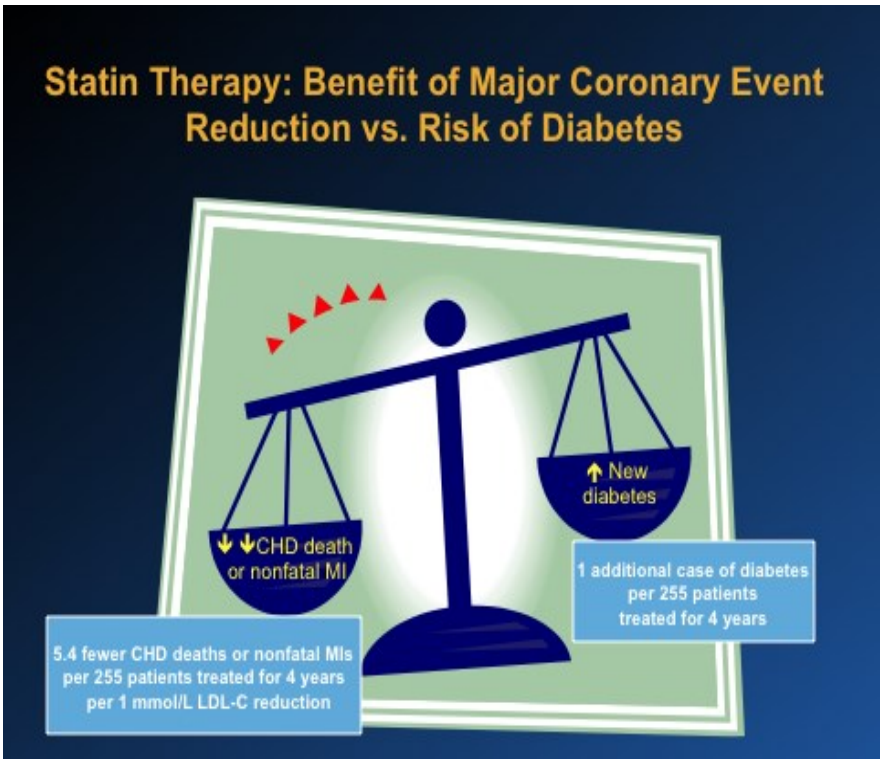
INTRODUCTION

In the current practice, statins are now the front-line agents in lowering the risk of cardiovascular disease (CVD). The choice of statin therapy is based on the patient group being treated, presence of and type of comorbidities, cost-effectiveness and the lipid target of that population. However according to recent studies, statins may increase the risk of diabetes. Diabetes is one of risk factor of CVD and it is ironic that statins have been linked with the risk of diabetes. The emergence of diabetes is a concern because of its associated complications and about two-thirds of deaths in people with diabetes were due to the CVD. Nevertheless, the protective effect of statins on CVD may suffice to support their use despite a potential risk of new-onset diabetes[1].

CURRENT FINDING

There have been conflicting findings to whether the use of statin increase the risk of diabetes. In 1995, James S. et al. reported that Pravastatin significantly reduce the incidence of diabetes in a randomized controlled trial (RCT) named the West of Scotland Coronary Prevention Study (WOSCOP)[2]. This result had led to more studies in evaluating the effect of statins on glycaemic control. In JUPITER RCT, the researchers found that Rosuvastatin had significantly increased the risk of diabetes. Thus, it raised the concern that the use of high intensity statin could actually worsen glycaemic control[3].

DOES STATIN THERAPY INCREASE THE RISK OF DIABETES?

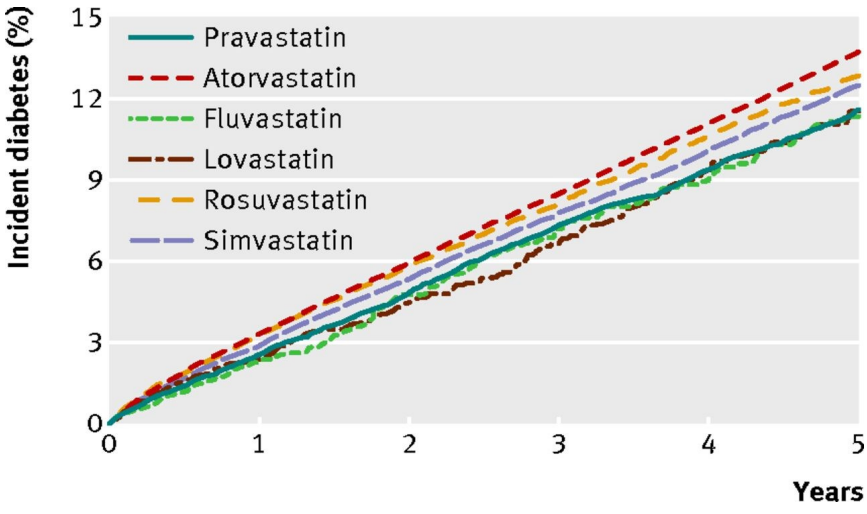


The debate continues when Sattar *et al.* (2010) revealed that statin therapy was associated with a higher incidence of diabetes risk during a mean follow-up of 4 years[4]. This meta-analysis involved 13 trials between 1994 and 2004 which includes 91, 140 non-diabetics patients comparing standard care with statins versus placebo. Overall, the result showed that there was an increased risk of diabetes (OR:1.09, 95% CI: 1.02-1.17) in the statin treated arm versus control[4]. When grouped by statins, Rosuvastatin showed significant increase in diabetes incidences (OR:1.18, 95% CI:1.04- 1.33) compared with other statins group. However, the study was unable to find out the predictors of outcome and the criteria used to diagnose diabetes varied from trial to trial. It was concluded that the increased risk of diabetes following statin treatment was small and that the benefits in cardiovascular risk clearly outweighed the incidence of diabetes[5].

Waters et al (2011) had analyzed 3 large RCTs: SPARCL, TNT and IDEAL which used Atovarstatin to examine the predictors of new onset of diabetes. It was reported that only the SPARCL study demonstrated a significant increase in the incidence of diabetes in patients on-80mg atorvarstatin compared to placebo whereas the two other studies did not show any significant differences when compared with lower dose statins[6]. It was also concluded that the diabetes risk was associated with fasting baseline blood sugar levels >5.6mmol/L, TG > 1.7mmol/L, BMI > 30 kg/m^2 and history of hypertension.

A meta-analysis was done by Preiss et al. in 2011 involving 5 trials comparing intensive dose statin therapy with moderate dose statin therapy in 32,752 patients. The group taking intensive dose statin was associated with an increase in new onset diabetes (OR 1.12, 95% CI 1.04-1.22)[7]. Nonetheless, this group developed fewer cardiovascular events.

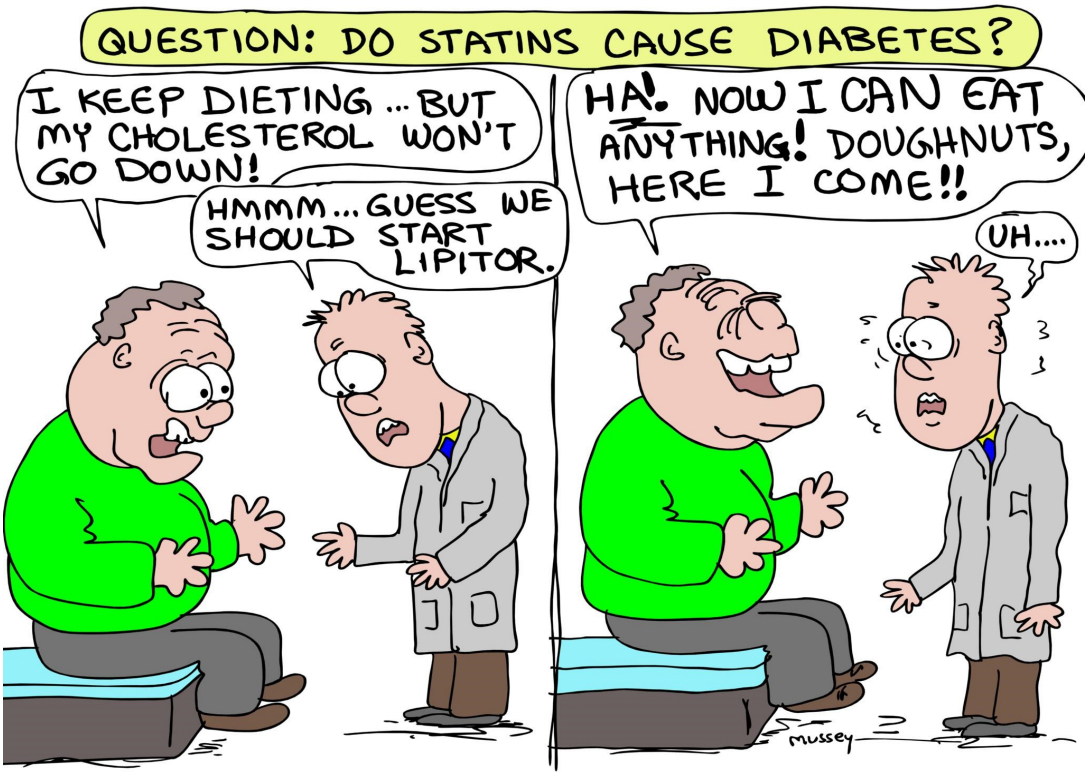
Lately, a study from Finland was carried out to investigate the mechanism underlying the risk of type 2 diabetes associated with statin treatment in the population-based Metabolic Syndrome in Men (METSIM) cohort. The study reported that statin therapy was associated with a 46% increased risk of type 2 diabetes after adjustment for confounding factors, suggesting a higher risk of diabetes in the general population than previously reported. It was deemed that statin therapy reduced insulin sensitivity by 24% and reduced insulin secretion by 12%, compared with individuals without statin therapy. These effects were demonstrated in the Simvastatin and Atovarstatin group and were shown to be dose -dependent[8].



Using Pravastatin as the standard comparator, a population based retrospective cohort study was carried out to compare the incidence of diabetes related to different statins. The study involved patients aged 66 or older without diabetes who started treatment with statins from 1 August 1997 to 31 March 2010 (n=471250). Compared with pravastatin, treatment with higher potency statins, especially atorvastatin and simvastatin, might be associated with an increased risk of new onset diabetes[9].

CONCLUSION

In conclusion, the use of statin seems to be associated with a slight increase of new onset diabetes although the strongest predictors of diabetes risk remain baseline fasting glucose and other features of the metabolic syndrome. There are many potential factors which could also increase the risk of diabetes with statin, thus healthcare professionals should plan the best intervention or management especially for those at risk of cardiovascular disease.



Drug Focus:
Seebri Breezhaler (Glycopyrronium Bromide) & Onbrez Breezhaler (Indacaterol)

Prepared By: Nur Amanina

COPD

- Inflammatory disease characterised by pulmonary airflow obstruction that is usually progressive and not fully reversible.
- Including chronic bronchitis, emphysema, lung damage which is caused by chronic asthma or any other risk factor like smoking tobacco.

Management:

- Bronchodilators : Beta2 agonist, anticholinergic, theophylline or combination therapy
- Inhaled corticosteroid
- Combination inhaled corticosteroids and bronchodilators
- Oral corticosteroids
- Phosphodiasterase -4-inhibitor
- Methylxantines

Seebri Breezhaler

Content
Contains 63 mcg glycopyrronium bromide equivalent to 50mcg glycopyrronium

What is Seebri Breezhaler?

♦ Seebri Breezhaler contains the active substance glycopyrronium bromide is an effective once daily long acting muscarinic antagonist (LAMA) bronchodilator.
It has rapid onset within 5 minutes after inhalataion (after 1st dose) in morning and Maintenance therapy for the treatment of the symptoms of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
Not indicated for the relief of an acute deterioration of COPD. [1,2]

Dosage

- The recommended dosage is the once daily inhalation of the content of one 50mcg capsule. (1puff /day)
- Can be inhale anytime after or before food and drinks.

Not to be used in patients under 18 years old.

Onbrez Breezhaler

Content

- 150mcg - contains 194 mcg indacaterol maleate equivalent to 150 mcg indacaterol
- 300mcg - contains 389 mcg indacaterol maleate equivalent to 300 mcg indacaterol

What is Onbrez Breezhaler?

- Onbrez Breezhaler contains the active substance indacaterol which is an ultra long-acting beta2-agonist (LABA) bronchodilator for once daily administration.
- It has a faster onset of action within 5 minutes after inhalation (first dose) and duration of effect consistent with 24 hours.[6]

Dosage

Adult

- The recommended dosage : one 150mcg capsule or one 300mcg capsule once daily depend on the patient condition.[6]
- 300 mcg capsule provide an extra benefit to some patient with regard to breathlessness or particularly for patients with severe COPD.
- The maximum dose is 300 microgram once-daily

Not to be used in patients under 18 years old.

Storage for both Breezhaler

- Do not store above 30°C.
- Store in the original package in order to protect from moisture and do not remove until immediately before use.
- Each inhaler should be disposed of after 30 days of use.

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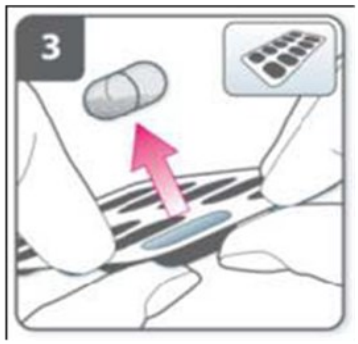
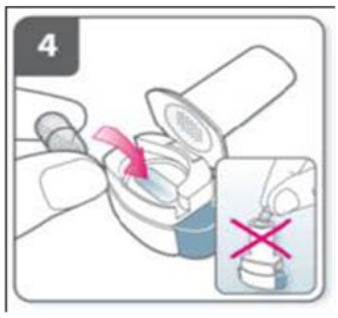
How to use??

Pull of cap

Open inhaler by tilt back mouthpiece

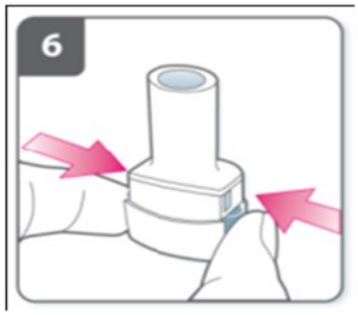


Prepare capsule



Place capsule in capsule chamber

Close inhaler until hear a click

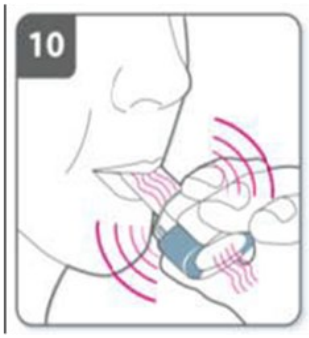


Pierce capsule by pressing both side buttons - click

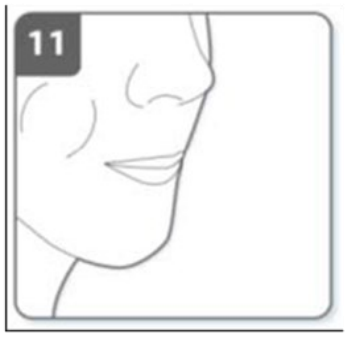
Release side buttons fully

Breathe out far from mouthpiece

Inhale the medicine rapidly but steadily as deeply as can



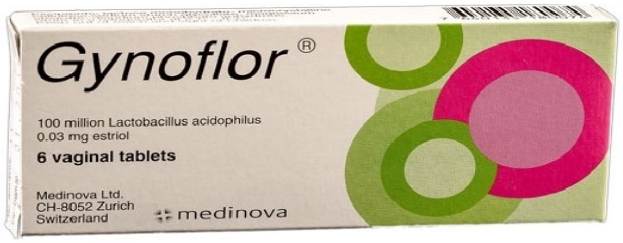
Hear whirring sound while inhale and experience sweet taste



Hold breath 5-10s and breath out

Open mouthpiece if got powder left inhale again if finish remove from chamber

Drug updates: Gynoflor®



Prepared By: Goh Jing Yi

What is gynoflor?

Gynoflor marketed by Medinova Switzerland contains of 100 million Lactobacillus acidophilus + 0.03mg Estriol and it is used for:

1. Restoration of lactobacillus flora after local and/or systemic treatment with anti-infective or chemotherapeutic agents. [1]
   Dosage: 1-2 vaginal tablets daily for 6-12 days. [1]
2. Atrophic vaginitis due to estrogen deficiency during menopause and post-menopause or as co-medication to systemic hormone replacement therapy. [1]
   Dosage: 1 vaginal tablet daily for 6-12 days, followed by a maintenance dose of 1 vaginal tablet on two consecutive days weekly for 12 weeks. [1, 2]

This vaginal tablet appears to be slightly beige, spotted, oval, biconvex. Patient shall insert it deeply into the vagina in the evenings before bedtime and this is best performed in a reclining position with the legs slightly bent. It can be moistened with a drop of water before insertion into a very dry vagina. [1] Gynoflor treatment should be interrupted during menstruation and resumed afterwards.

STORAGE

-Gynoflor shall be stored in a refrigerator at 2-8°C. -Storage of Gynoflor at room temperature during the treatment period (1-2 weeks) does not affect its efficacy. [1]

Who are being contraindicated?

- People who are hypersensitive to *Lactobacillus acidophilus* and estriol or to any of the excipients of Gynoflor shall be contraindicated from use of Gynoflor.
- Malignant changes (estrogen-dependent tumors) in breast, uterus or vagina; endometriosis (suspected or manifested); vaginal hemorrhaging of unknown origin are another reasons for it to be contraindicated.
- Use of Gynoflor is absolutely contraindicated in young girls who have not reached sexual maturity. [1]

Special precautions/ interaction

-Patients should not use vaginal douches or rinses during treatment of Gynoflor.
-Gynoflor can be used in pregnancy and lactation. However, caution should be exercised when prescribing Gynoflor to pregnant women in the 1st trimester. [1]
-*Lactobacillus acidophilus* is sensitive to various anti-infective agents (local or systemic). Simultaneous treatment of such agents may lead to a reduction in efficacy of Gynoflor. [1]

Safety and tolerability

Adverse effects which are mainly local reactions (mild stinging, burning, irritation, pruritus, reddening, local allergic reactions) are being reported. Most of the adverse effects are mild and occurred temporarily during initiation of therapy. [3]
Estriol (E3) which is specific for humans is unable to induce estrogenic effects on endometrium, bone and breast tissue at physiological concentrations due to its low receptor affinity. In normal vaginal doses (≤0.5 mg), E3 does not have or have only a weak proliferative effect on endometrium after single-dose of vaginal applications. [8]

Most of the adverse effects are mild and occurred temporarily during initiation of therapy.

How it acts?

Lactobacillus acidophilus which are dominant vaginal mutualists produces hydrogen peroxide (H_2O_2) and other antimicrobial substances such as bacteriocins and bacteriocin-like substances to inhibit growth of pathogenic microorganisms. H_2O_2 is an oxidizing agent which kills pathogens through the production of free radicals. It is thought that lactobacilli produce Fe3+-activated extracellular peroxidase to protect themselves. [3] In addition to that, it competes with other microorganisms such as *Escherichia coli, Salmonella typhimurium, Candida albicans, Staphylococcus aureus* for adherence to the vaginal epithelium and for nutrients. Thus, prevents the pathogens colonization of the vagina by competitive exclusion. [3] It ferments glycogen stored in the vaginal epithelium to lactic acid, resulting in a normal (<4.5) vaginal pH. The resulting acidic environment is an optimal medium for the proliferation of the Lactobacilli and unfavourable for the colonisation and growth of pathogenic microorganisms. [1,3]

Estriol (E3) is an endogenous estrogenic hormone which has a specific effect on vagina but not on the endometrium. [1] Estriol stimulates the proliferation and maturation of vaginal epithelium. A proliferated and matured vaginal epithelium acts as physical barrier and stores glycogen, a nutritional substrate for lactobacilli. However, vaginal epithelium is disturbed and the glycogen content is decreased in the case of hormonal disorders. This is more commonly observed at advanced age. Low dose estriol, is able to improve the proliferation and maturation of the epithelium, and thus provides the optimal conditions for the restoration of the vaginal lactobacilli flora. It has been shown that the in vitro adherence of lactobacilli to vaginal epithelial cells is stronger on days of high concentrations of estrogens. [3]

Clinical efficacy

Ozkinay et al. [5] evaluated the effectiveness of live lactobacilli in combination with low dose oestriol for restoration of the vaginal flora after anti-infective treatment in single centre, randomised, placebo-controlled, double-blind clinical trial. 360 women with the complaints of vaginal infections were randomly assigned to Gynoflor therapy after the end of the anti-infective therapy and the Normal Flora Index (NFI) was used as the primary outcome of the study. It was found out that the Normal Flora Index (NFI) was significantly improved in test group and authors suggested that restoration of the vaginal flora can be significantly enhanced by the administration of Gynoflor.

Long term prevention of bacterial vaginosis recurrence has been investigated using repeated probiotic lactobacilli therapy and promising results were shown in earlier studies conducted. [6, 7]

In a multi-centre, randomised, single-blind, active-controlled pilot study conducted by Donders et al. [4], efficacy of lyophilized lactobacilli in combination with 0.03 mg estriol was compared to metronidazole in the treatment of bacterial vaginal infections in 46 pre-menopausal women (aged between 18 to 50 years) with a disrupted vaginal flora. Patients were given a blinded box with either 12 vaginal tablets of Gynoflor® or 6 vaginal suppositories containing 500 mg metronidazole and status of the vaginal flora was studied at entry, 3-7 days (control 1), 4-6 (control 2) weeks and 4 months after the end of therapy. This study showed that efficacy of short-term treatment of bacterial vaginal infections using lyophilized lactobacilli in combination with low-dose estriol are equivalent to metronidazole, but efficacy was lesser after 1 month.

In the treatment of vaginal atrophy, Jaisamrarn et al. [2] conducted a double-blind, randomized, placebo-controlled study followed by an open-label follow-up to evaluate the efficacy of Gynoflor in short-term therapy and to investigate the long-term maintenance dose in the treatment of vaginal atrophy. Postmenopausal women with vaginal atrophy symptoms and Vaginal Maturation Index (VMI) of ≤40% were included into the studies. Subjects were given with initial therapy of test medication (or placebo in first phase), one vaginal tablet daily for 12 days, followed by maintenance therapy, one tablet on two consecutive days weekly for 12 weeks. Study revealed that Gynoflor was superior to placebo with respect to positive changes in VMI after the 12-day initial therapy, and authors suggested the maintenance therapy of two tablets weekly was sufficient to

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COUNSELLING CORNER : FORTRANS MACROGOL 4000

Prepared By: Raja Ainul

Fortrans consists of Macrogol 4000, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride, Sodium Sulfate Anhydrous is an osmotic laxatives.

Fortrans is used for the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis.

⇒ fortrans is carrying water to stool, which loosens and increases stool volume, helping to overcome sluggish bowels
⇒ working gradually within 24 to 48 hours
⇒ not absorbed into the bloodstream or broken down in the body.
⇒ treatment of constipation in adults and children aged 8 years and above.

Indication:

* as an electrolyte replenisher & treatment of hypokalemia
* Osmotic laxative used for colon lavage to prepare patients prior to:
* Endoscopic or radiological investigations
* colon surgery

Dosage & administration:

* The contents of each sachet are dissolved in about 1L of drinking water.
* When morning surgery is planned, the oral solution is given in the late afternoon the day prior. If surgery is scheduled for the afternoon, the oral solution should be given on the same day for ingestion to be completed three hours before surgery.
* 3-4L of oral solution are required to obtain an effective lavage.

Do not take Macrogol 4000:

* If you are allergic to macrogol (polyethylene glycol) or any of the other ingredients of this medicine
* If have severe intestinal disease - inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or abnormal dilation of the bowel.
* Painful belly of unknown cause

If forget to take Macrogol 4000

* Take the next dose as soon as you remember.
* Do not take a double dose to make up for a forgotten dose.
* If you do not feel better or if you feel worse after 14 days you must contact a doctor.

If you develop any of the following symptoms. contact your doctor immediately:

Allergic reactions (rash, hives, swelling of the face or throat, breathing difficulties, faintness or collapse) (frequency not known, frequency cannot be estimated from the available data)

Storage

* Keep this medicine out of the sight and reach of children.
* Do not use this medicine after the expiry date
* Do not store above 30°C. Store in its original container to protect from light

BOWEL PREPARATION USING FORTRANS :

DAY BEFORE EXAMINATION	
Breakfast, Lunch, and **Dinner**	Take **Plain white bread, plain porridge or fish porridge** **DO NOT** consume any **vegetables, fruits, or red meats**. **DO NOT** take **milk/milk products ie Milo** **DO NOT** take **wholemeal bread, cereals, oats & nuts** **No solid food** is to be taken **after 6pm**. You are only allowed to drink clear fluids (ie plain water, glucose, 100 plus with gas stirred out, tea or coffee without milk) when necessary.
7pm - 8pm	**1 sachet of Fortrans + 1 liter of water** Drink slowly, one glassful at a time until all the solution is consumed **within 1 hour.** Bowel evacuation will begin within 1-2 hours after consuming Fortrans solution.
8pm - 9pm	**1 sachet of Fortrans + 1 liter of water** Drink slowly, one glassful at a time until all the solution is consumed **within 1 hour**.
DAY OF EXAMINATION	
5am - 6am	**1 sachet of Fortrans + 1 liter of water** Drink slowly, one glassful at a time until all the solution is consumed **within 1 hour**.

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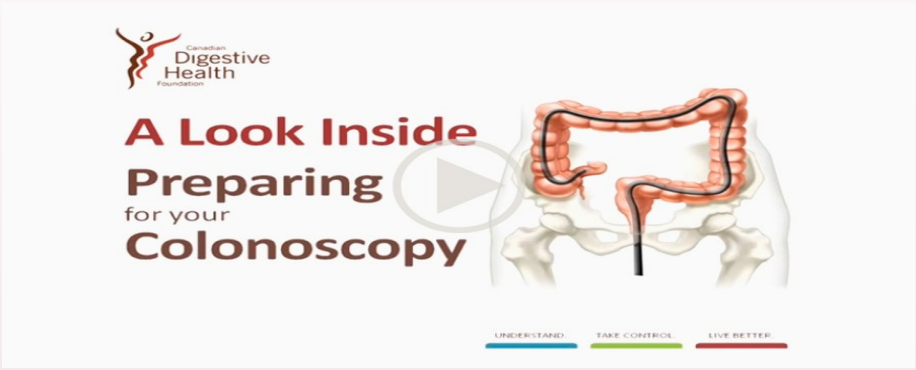
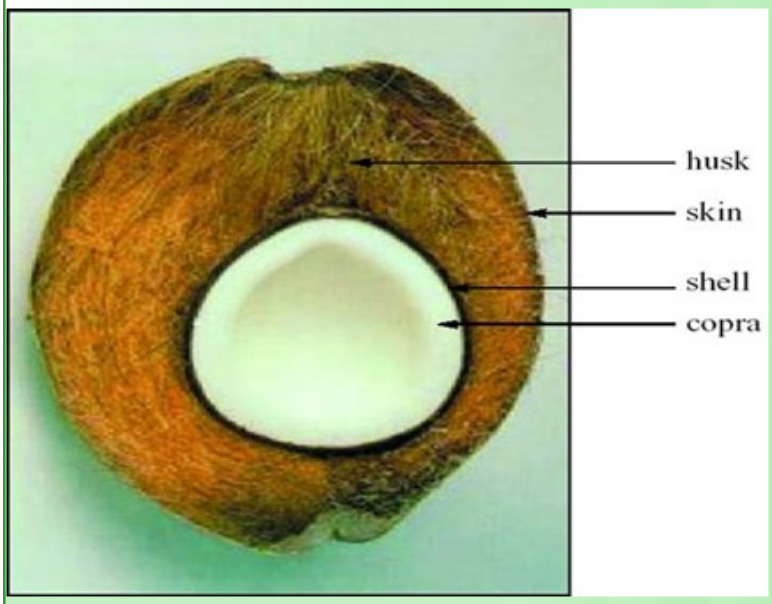


Prepared By: Aisyah Amanina



Coconut water is a natural water and clear liquid that found most abundantly inside young, green coconuts, which are fruits of the coconut palm. It has a sweet, nutty taste and contains 5.45 calories, 1.3 grams sugar, 61 miligrams of potassium and 5.45 miligrams of sodium[1].

Researchers identified there are 12 essential amino acids, including cystine, methonine, valine, leucine and histidine in the coconut water. Latest investigation reported coconut water as being a good source of vitamin B1 & B2. Its specific gravity & PH closely approximate that of blood plasma[2] .

Coconut water has a positive nutritional contribution to diet as it is low in calories, naturally fat and cholesterol free. Hence, it can be used to replace high calorie, non-nutritional beverages.

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Benefits of coconut water

1. **High in healthful antioxidants** [3]

A research study showed coconut water has a good antioxidant potential. They studied four coconut varieties; green dwarf, yellow dwarf, red dwarf and yellow Malaysia. Among the four coconut varieties, green dwarf showed the best result in scavenging DPPH radical and has the highest level of phenols and vitamin C[4].

2. Replenishes body fluids and nutrients in the body [3]

Coconut water could be used for whole body rehydration after exercise-induce dehydration. It is easier to consume a larger amount of coconut water when compared to plain water and carbohydrate-electrolyte beverages.

3. An excellent growth medium for the production of food yeast (*Saccharomyces fragilis*)[2]

Hence, to use only those coconuts with intact shells, freshly opened

4. Remedy for diarrhea[5]

Young coconut water can be used as a home glucose electrolyte oral rehydration solution in the early stages of mild diarrhea disease.

5. Helps to lower bad cholesterol level[6]

Recent study showed coconut water has lipid lowering effect similar to the drug lovastatin in rats fed fat–cholesterol enriched diet. As the coconut water presents a series of nutritional and therapeutic properties, being a natural, acid and sterile solution, which contains several biologically active components, l-arginine, and ascorbic acid, minerals such as calcium, magnesium and potassium, which have beneficial effects on lipid level.