

類 科：藥事

科 目：調劑學與臨床藥學

考試時間：2小時

座號：_____

※注意：(一)禁止使用電子計算器。

(二)不必抄題，作答時請將試題題號及答案依照順序寫在試卷上，於本試題上作答者，不予計分。

一、下面加框內文為美國 FDA 於 2016 年 4 月 8 日發布有關 metformin 安全訊息的片段。

(一)依據現今醫學指引，metformin 在糖尿病治療的地位為何？有何優點與缺點？一般劑量為何？(12分)

(二)請問以前 metformin 在腎功能不佳的病人不能使用，是參考何種參數？該參數於多少時不能使用？(5分)

(三)根據此訊息，使用 metformin 之病人在何種狀況應停藥？(5分)

FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function

- FDA is requiring manufacturers to revise the labeling of metformin-containing drugs to indicate that these products may be safely used in patients with mild to moderate renal impairment.
- We are also requiring manufacturers to revise the labeling to recommend that the measure of kidney function used to determine whether a patient can receive metformin be changed from one based on a single laboratory parameter (blood creatinine concentration) to one that provides a better estimate of renal function (i.e., glomerular filtration rate estimating equation (eGFR)). This is because in addition to blood creatinine concentration, the glomerular filtration rate takes into account additional parameters that are important, such as the patient's age, gender, race and/or weight.
- The labeling recommendations on how and when kidney function is measured in patients receiving metformin will include the following information:
 - ◆ Before starting metformin, obtain the patient's eGFR.
 - ◆ Metformin is contraindicated in patients with an eGFR below 30 mL/minute/1.73 m².
 - ◆ Starting metformin in patients with an eGFR between 30-45 mL/minute/1.73 m² is not recommended.
 - ◆ Obtain an eGFR at least annually in all patients taking metformin. In patients at increased risk for the development of renal impairment such as the elderly, renal function should be assessed more frequently.
 - ◆ In patients taking metformin whose eGFR later falls below 45 mL/minute/1.73 m², assess the benefits and risks of continuing treatment. Discontinue metformin if the patient's eGFR later falls below 30 mL/minute/1.73 m².
 - ◆ Discontinue metformin at the time of or before an iodinated contrast imaging procedure in patients with an eGFR between 30 and 60 mL/minute/1.73 m²; in patients with a history of liver disease, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart metformin if renal function is stable.

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二、請依據下列案例回答下列問題，並填寫「藥品不良反應評檢表」。

(一)病人發生何種不良反應？引起不良反應的藥品及原因為何？該不良反應屬於 type A 或 type B 反應，為什麼？（8分）

(二)你會建議醫師怎樣處理？（6分）

Wu, a 68-year-old male with Hx of cardiomyopathy, AF and HTN, had been treated with dipyridamole 75 mg tid, digoxin 0.125mg qd, and valsartan 80 mg qd. One week after addition of amiodarone 200 mg bid for refractory AF, he experienced syncope at home. At that time, his BP was 90/40, and HR was 40. He woke after lying down for 3 minutes. After consulting the doctor, amlodipine, digoxin and amiodarone were hold. His BP was 110/60 with a HR of 60 the next day. Digoxin and amlodipine were resumed afterwards. Patient did well until 1 week after resumption of amiodarone, when another episode of syncope occurred.

(三)依照「藥品不良反應評檢表」，該不良反應與該藥品的相關性及評分如何？請逐項解釋。（11分）

藥品不良反應評檢表				
可能性：為評估藥品不良反應，請回答下列問題並勾選適當的答案。				
	是	否	不知	給分
1. 以前是否有關於此種不良反應確定的研究報告？	+1	0	0	
2. 此種不良反應是否於服藥之後發生？	+2	-1	0	
3. 當停藥或服用此藥之解藥，不良反應是否減輕？	+1	0	0	
4. 停藥一段時間再重新服用此藥，同樣的不良反應是否再度發生？	+2	-1	0	
5. 有沒有其他原因（此藥品以外）可以引起同樣的不良反應？	-1	+2	0	
6. 當給予安慰劑時，此項不良反應是否也會再度發生？	-1	+1	0	
7. 此藥品的血中濃度是否達到中毒劑量？	+1	0	0	
8. 對此病人而言，藥品劑量與不良反應的程度是否成正向關係？	+1	0	0	
9. 病人過去對同樣或類似藥品是否也產生同樣的不良反應？	+1	0	0	
10. 此項不良反應是否有客觀的證據？	+1	0	0	
				總分
確定為下列何者：				
_____ > 8 分，確定	_____ 1-4分，可能			
_____ 5-8分，極有可能	_____ = 0分，存疑	_____ < 0分，不相關		

（請接第三頁）

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三、食品藥物管理署在 104 年 6 月 26 日正式公告「藥品仿單應刊載賦形劑成分名或品名」，請回答下列三個問題：

(一)依據學理，為什麼藥品仿單必須刊載賦形劑成分名或品名？請舉例說明。(5分)

(二)藥品賦形劑有那些類別？(10分)

(三)同一成分可能有不同作用，下列成分分別屬於那類賦形劑？(10分)

- 1.Sodium metabisulfite
- 2.Acacia
- 3.Mannitol
- 4.Polyethylene glycol
- 5.Difluoroethane
- 6.Butylparaben
- 7.Lecithin
- 8.Glycerin
- 9.Carnauba wax
- 10.Alcohol

四、下列藥品合併使用時，會發生何種交互作用？屬於那種型態（快速或延遲型）？作用機制？可否用間隔服用避開？請依序回答。(每小題4分，共16分)

(一) Voriconazole + St. John's wort

(二) Digoxin + verapamil

(三) Cyclosporine + sirolimus

(四) Daclatasvir + rifampin

五、請問下列抗體藥品的種類（依照帶有老鼠基因比例分類）、藥理分類（機轉）及臨床用途？（每小題3分，共12分）

(一) Adalimumab

(二) Basiliximab

(三) Muromonab-CD3 (OKT3)

(四) Tocilizumab