

**立法會**  
***Legislative Council***

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Tel : 2869 9205

Date : 1 December 2003

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

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**Council meeting of 17 December 2003**

**Proposed resolutions under the Pharmacy and Poisons Ordinance**

I forward for Members' consideration two proposed resolutions which the Secretary for Health, Welfare and Food will move at the Council meeting of 17 December 2003 under the Pharmacy and Poisons Ordinance. The President has directed that "it be printed in the terms in which it was handed in" on the Agenda of the Council.

2. The speech, in both English and Chinese versions, which the Secretary will deliver when moving the proposed resolutions, and the supplementary information provided by the Secretary, are also attached.

(Ray CHAN)  
for Clerk to the Legislative Council

Encl.

## PHARMACY AND POISONS ORDINANCE

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### **RESOLUTION**

(Under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138))

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RESOLVED that –

- (a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2003; and
- (b) the Poisons List (Amendment) (No. 4) Regulation 2003, made by the Pharmacy and Poisons Board on 26 November 2003, be approved.

**PHARMACY AND POISONS (AMENDMENT) (NO. 4)  
REGULATION 2003**

(Made by the Pharmacy and Poisons Board under section 29  
of the Pharmacy and Poisons Ordinance (Cap. 138)  
subject to the approval of the Legislative Council)

**1. Substances falling within the Poisons List to  
which special restrictions apply under  
regulations 3 and 5**

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub.  
leg. A) is amended in part A –

(a) by adding –

“Adalimumab  
Anagrelide; its salts  
Bosentan; its salts  
Darbepoetin alfa  
Dutasteride  
Gefitinib; its salts  
Memantine; its salts  
Rosuvastatin; its salts  
Vardenafil; its salts”;

(b) in the item relating to “Contrast media”, by adding –

“Ferucarbotran  
Gadobutrol  
Sulphur Hexafluoride”.

**2. Substances required by regulation 9 to be  
sold by retail only upon a prescription  
given by a registered medical  
practitioner, registered dentist or  
registered veterinary surgeon**

The Third Schedule is amended in part A –

(a) by adding –

“Adalimumab  
Anagrelide; its salts  
Bosentan; its salts  
Darbepoetin alfa  
Dutasteride

Gefitinib; its salts  
Memantine; its salts  
Rosuvastatin; its salts  
Vardenafil; its salts”;

- (b) in the item relating to “Contrast media”, by adding –  
“Ferucarbotran  
Gadobutrol  
Sulphur Hexafluoride”.

(Dr. P. Y. LAM)  
Chairman,  
Pharmacy and Poisons Board

26 November 2003

### **Explanatory Note**

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) by adding 12 substances to each of them.

## **POISONS LIST (AMENDMENT) (NO. 4) REGULATION 2003**

(Made by the Pharmacy and Poisons Board under section 29  
of the Pharmacy and Poisons Ordinance (Cap. 138)  
subject to the approval of the Legislative Council)

### **1. The Poisons List**

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in part A –

(c) by adding –

“Adalimumab  
Anagrelide; its salts  
Bosentan; its salts  
Darbepoetin alfa  
Dutasteride  
Gefitinib; its salts  
Levodropropizine; its salts  
Memantine; its salts  
Rosuvastatin; its salts  
Vardenafil; its salts”;

(d) in the item relating to “Contrast media”, by adding –

“Ferucarbotran  
Gadobutrol  
Sulphur Hexafluoride”.

(Dr. P. Y. LAM)  
Chairman,  
Pharmacy and Poisons Board

26 November 2003

**Explanatory Note**

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) by adding 13 substances to part A of Part I of the Poisons List.

**Poisons List (Amendment) (No. 4) Regulation 2003**

**Pharmacy and Poisons (Amendment) (No. 4) Regulation 2003**

**Supplementary Information to the Legislative Council**

**《2003 年毒藥表（修訂）（第四號）規例》**

**《2003 年藥劑業及毒藥（修訂）（第四號）規例》**

提交立法會的補充資料

<b>Drug Name 藥名</b>	<b>Proposed Classification 建議類別</b>	<b>Reason 原因</b>
Adalimumab (阿達木單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒 藥	<p>This drug is used for relief of rheumatoid arthritis when other medicines have failed to work. Use of this drug requires medical decision and monitoring.</p> <p>經使用其它藥物無效之後，此藥用作舒緩類風濕性關節炎的症狀。選用此藥需經醫生決定及觀察。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Anagrelide; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used for thrombocythaemia, a disease in which there is an increased number of platelets in the blood. It should be used after confirmed medical diagnosis and under careful monitoring.</p> <p>此藥用作治療血小板增多症。需經醫生確定診症後才用藥而病人需被小心觀察。</p>
Bosentan; its salts (波生坦;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat raised blood pressure within the blood vessels supplying the lungs. It should be used after confirmed medical diagnosis and under careful monitoring by a doctor.</p> <p>此藥用作治療肺動脈高壓。需經醫生確定診症後才用藥而病人需被小心觀察。</p>
Darbepoetin alfa	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat anaemia associated with kidney failure. Use of this drug requires medical decision and monitoring.</p> <p>此藥用作治療腎衰竭引致之貧血。選用此藥需經醫生決定及觀察。</p>



<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Dutasteride (度他雄胺)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat moderate to severe symptoms of benign prostate enlargement and reduce the risk of acute urinary retention and surgery for these patients. A doctor's decision is required on whether or not to use this medicine.</p> <p>此藥用於治療中度至嚴重良性前列腺肥大症狀及減少此類病人急性閉尿症和需做手術之風險。選用此藥需經醫生決定。</p>
Gadobutrol; its salts (釐布醇;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used as a contrast medium in magnetic resonance imaging of the head and spine. Medical decision is required for the use of this drug.</p> <p>此藥用作頭和脊骨磁力共振掃描的造影劑。選用此藥需經醫生決定。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Gefitinib; its salts (吉非替尼;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat advanced or metastatic Non Small Cell Lung Cancer after other drugs failed. It should be used after confirmed medical diagnosis and under careful monitoring.</p> <p>此藥用於治療已經使用其它藥物而無效的末期或已擴散之非小細胞肺癌。需經醫生確定診症後才用藥而病人需被小心觀察。</p>
Ferucarbotran; its salts (鐵羧葡胺;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used as a contrast medium in magnetic resonance imaging. Medical decision is required for the use of this drug.</p> <p>此藥用作磁力共振掃描的造影劑。選用此藥需經醫生決定。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Levodropropizine; its salts  (左旋羥丙哌嗪；其鹽類)	Part I poison 第一部毒藥	<p>This drug is used to treat persistent cough but should not be used when there is excessive discharge of mucus. Patients may become drowsy after taking this medicine. Professional advice is required from a pharmacist for proper usage of this drug.</p> <p>此藥用於治療久咳，但不應用於過多黏痰之咳嗽。病人亦可能會感到昏昏欲睡。需由藥劑師提供專業指示才服用此藥。</p>
Memantine; its salts  (美金鋼；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used for the treatment of moderately severe to severe Alzheimer's disease (progressive form of mental disorder, marked by memory loss, occurring in middle age). Medical decision is required for the use of this drug.</p> <p>此藥用於治療中度至嚴重的早老性痴呆症。需經醫生決定後才用藥。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Rosuvastatin; its salts (瑞舒伐他汀； 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒 藥	<p>This drug is used to lower high blood cholesterol level after non-drug measures failed. This drug should not be used in patients with active liver disease and may cause increase in liver enzymes levels in patients. Liver function tests are required prior to, and 3 months following initiating treatment. Use of this drug requires medical decision and monitoring.</p> <p>此藥用於經非藥物治療失敗後以降低血內的過高膽固醇含量。有活躍肝病的病人不應服用此藥，而此藥亦可能令病人肝酵素上升。用藥前及用藥三個月內，需檢查肝臟功能。選用此藥需經醫生決定及觀察。</p>
Sulphur Hexafluoride (六氟化硫)	Part I, First and Third Schedules poison 第一部附表一及附表三毒 藥	<p>This drug is used as a diagnostic aid in ultrasound imaging. Use of this drug requires medical decision.</p> <p>此藥用作超聲波掃描的造影劑。選用此藥需經醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Vardenafil; its salts (伐地那非；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat erectile dysfunction. This drug should not be used in patients taking certain cardiac drugs and those who have severe liver impairments and end stage kidney disease, hypotension, recent history of stroke or heart attacks. Medical decision is required for the use of this drug.</p> <p>此藥用於治療勃起障礙。此藥不應用於正在服用某些心臟藥的病人或有嚴重肝損害、末期腎病、血壓低和近期有中風或心臟病發記錄的病人。選用此藥需經醫生決定。</p>

## PHARMACY AND POISONS ORDINANCE

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### **RESOLUTION**

(Under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138))

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RESOLVED that –

- (a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2003; and
- (b) the Poisons List (Amendment) (No. 5) Regulation 2003, made by the Pharmacy and Poisons Board on 26 November 2003, be approved.

**PHARMACY AND POISONS (AMENDMENT) (NO. 5)  
REGULATION 2003**

(Made by the Pharmacy and Poisons Board under section 29  
of the Pharmacy and Poisons Ordinance (Cap. 138)  
subject to the approval of the Legislative Council)

**1. Commencement**

This Regulation shall come into operation on 19 January 2004.

**2. Substances falling within the Poisons List to  
which special restrictions apply under  
regulations 3 and 5**

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub.  
leg. A) is amended in part A, by adding –

“Benzbromarone  
Mesalazine; its salts  
Nadroparin; its salts  
Naftidrofuryl; its salts  
Nalidixic acid  
Nicergoline  
Pantethine; its salts  
Pipemidic acid  
Pralidoxime; its salts  
Pridinol; its salts  
Protirelin; its salts  
Pyricarbate (Pyridinolcarbamate)  
Sermorelin; its salts  
Somatostatin  
Streptokinase  
Tranexamic acid  
Trifluridine; its salts  
Trimethoprim  
Tromantadine; its salts  
Urokinase”.

**3. Substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon**

The Third Schedule is amended in part A, by adding –

“Benzbromarone  
Mesalazine; its salts  
Nadroparin; its salts  
Naftidrofuryl; its salts  
Nalidixic acid  
Nicergoline  
Pantethine; its salts  
Pipemidic acid  
Pralidoxime; its salts  
Pridinol; its salts  
Protirelin; its salts  
Pyricarbate (Pyridinolcarbamate)  
Sermorelin; its salts  
Somatostatin  
Streptokinase  
Tranexamic acid  
Trifluridine; its salts  
Trimethoprim  
Tromantadine; its salts  
Urokinase”.

(Dr. P. Y. LAM)  
Chairman,  
Pharmacy and Poisons Board

26 November 2003



**Explanatory Note**

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) by adding 20 substances to each of them.

## **POISONS LIST (AMENDMENT) (NO. 5) REGULATION 2003**

(Made by the Pharmacy and Poisons Board under section 29  
of the Pharmacy and Poisons Ordinance (Cap. 138)  
subject to the approval of the Legislative Council)

### **1. Commencement**

This Regulation shall come into operation on 19 January 2004.

### **2. The Poisons List**

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in part A, by adding –

“Benzbromarone  
Mesalazine; its salts  
Nadroparin; its salts  
Naftidrofuryl; its salts  
Nalidixic acid  
Nicergoline  
Pantethine; its salts  
Pipemidic acid  
Pralidoxime; its salts  
Pridinol; its salts  
Protirelin; its salts  
Pyricarbate (Pyridinolcarbamate)  
Sermorelin; its salts  
Somatostatin  
Streptokinase  
Tranexamic acid  
Trifluridine; its salts  
Trimethoprim  
Tromantadine; its salts  
Urokinase”.

(Dr. P. Y. LAM)  
Chairman,  
Pharmacy and Poisons Board

26 November 2003

**Explanatory Note**

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) by adding 20 substances to part A of Part I of the Poisons List.

## Poisons List (Amendment) (No. 5) Regulation 2003

### Pharmacy and Poisons (Amendment) (No. 5) Regulation 2003

#### Supplementary Information to the Legislative Council

《 2003 年毒藥表（修訂）（第五號）規例 》

《 2003 年藥劑業及毒藥（修訂）（第五號）規例 》

提交立法會的補充資料

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Benzbromarone (苯溴馬隆)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This drug is used for treatment of long-term high uric acid levels. Serious hepatic reactions, including liver failure and fulminant hepatitis, have been reported. Medical decision is required to diagnose the condition and medical supervision is required during administration.</p> <p>此藥用於治療慢性高尿酸。用藥後曾有報導指出會產生嚴重肝反應，包括肝衰竭及暴發性肝炎。用藥前需經醫生斷症而用藥時亦需由醫生監督。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Mesalazine; its salts (美沙拉秦;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat acute attacks of inflammation and ulceration of colon and rectum or maintenance of remission of such conditions. It is also used in Crohn's disease (inflammation and ulceration of the alimentary tract). Possible side effects include hepatitis, and blood disorders. Medical decision is required to diagnose the disease and medical supervision is required during administration.</p> <p>此藥用於治療急性結腸及直腸發炎及潰瘍，或預防其復發。此藥亦用於克羅恩氏病(消化道發炎及潰瘍)。可能的副作用包括肝炎及血液系統疾病。用藥前需經醫生斷症而用藥時亦需由醫生監督。</p>
Nadroparin; its salts (那屈肝素;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat and prevent venous thromboembolism (dislodged bloodclot) and prevent clotting during extracorporeal circulation. Medical decision is required to diagnose the condition and medical supervision is required during administration.</p> <p>此藥用於治療及預防靜脈血栓栓塞和預防體外血液循環的血凝固。用藥前需經醫生斷症而用藥時亦需由醫生監督。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Naftidrofuryl; its salts (萘呋啉;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat blood circulatory disorders. Hepatic reactions have occurred. The need to use this drug should be established by medical diagnosis.  此藥用於治療血液循環系統疾病。 用藥曾引致肝臟副作用。選用此藥 需經醫生斷症適用。
Nalidixic acid (萘啶酸)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat lower urinary tract infections and dysentery. Blood counts, renal and hepatic functions should be monitored if treatment continues for more than 2 weeks. Medical decision is required on the use of this drug.  此藥用於治療下尿道感染及痢疾。 如用藥超過兩星期, 需觀察病人的 血細胞數據, 腎和肝功能。需經醫生 決定才用此藥。

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Nicergoline (尼麥角林)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used in the treatment of symptoms of mental deterioration associated with blood circulatory disorders. It should not be used in patients with porphyria. This drug should only be used when the need is established by medical diagnosis.  此藥用於治療因血液循環系統疾病引致的精神變壞。有卟啉症病人不可服用此藥。選用此藥需經醫生斷症適用。
Pantethine; its salts (泛硫乙胺;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat high levels of blood lipids. The need to use this drug should be established by medical diagnosis.  此藥用於治療過高血脂。選用此藥需經醫生斷症適用。
Pipemidic acid (吡哌酸)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat urinary tract infections. The need to use this drug should be established by medical diagnosis.  此藥用於治療尿道炎。選用此藥需經醫生診斷適用。

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Pralidoxime; its salts (解磷定;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat poisoning due to chemicals such as insecticides. Medical decision and monitoring are required for the use of this drug.  此藥用於治療化學物品中毒，例如殺蟲藥。選用此藥需經醫生決定及觀察。
Pridinol; its salts (普立地諾;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to relieve muscle spasms and is not suitable for patients with glaucoma and severe heart diseases. Medical decision and monitoring are required for the use of this drug.  此藥用於舒緩肌肉痙攣。患有青光眼和嚴重心臟病病人不可服用此藥。選用此藥需經醫生決定及觀察。
Protirelin; its salts (普羅瑞林;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to diagnose the disorders of the thyroid glands and ophthalmic Graves' disease. This drug can affect blood pressure and pulse. Medical decision is required on whether or not to use this drug.  此藥用於診斷甲狀腺疾病及突眼性甲狀腺腫。此藥可影響血壓和脈搏。選用此藥需經醫生決定。



<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Pyricarbate (Pyridinolcarbamate) (吡卡酯)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat blood clotting, high blood lipid levels and circulatory disorders. Liver damage may occur. The need to use this drug should be established by medical diagnosis.  此藥用於治療血凝固, 高血脂及循環系統疾病。用藥可引致肝臟損壞。選用此藥需經醫生斷症適用。
Sermorelin; its salts (舍莫瑞林; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used for diagnosis and treatment of growth hormone deficiency in children. It is also used to help in the induction of ovulation. Medical decision is required on whether or not to use this drug.  此藥用於診斷及治療兒童生長激素缺乏症, 亦用於協助引導排卵。需經醫生決定才用此藥。
Somatostatin (生長抑素)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat bleeding of the gastrointestinal tract and tried in other hormonal secretory disorders. Medical decision and monitoring are required for the use of this drug.  此藥用於治療腸胃道流血, 及試用於其它賀爾蒙失調症。用此藥時需經醫生決定及觀察。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Streptokinase (鏈激酶)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat blood clot dislodging disorders such as heart attacks. The need to use this drug requires medical diagnosis. The patient concerned should be under monitoring during administration.  此藥用於治療血栓栓塞症，如心肌梗塞。選用此藥需經醫生斷症而病人應於用藥時需接受觀察。
Tranexamic acid (氨甲環酸)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat and prevent bleeding caused by breakdown of blood clotting factors. The need to use this drug requires medical diagnosis.  此藥用於治療及預防因凝血因子溶解引致的出血。選用此藥需經醫生斷症適用。
Trifluridine; its salts (曲氟尿苷;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to treat inflammation of the cornea and conjunctiva of the eye, and recurrent viral infection of the cornea. Prolonged use may damage the cornea. A doctor's decision is required for the use of this drug.  此藥用於治療結膜及角膜的發炎，及經常性角膜病毒感染。長期使用可引致角膜受損。選用此藥需經醫生決定。

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Trimethoprim (甲氧苄啶)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat infections of the gastrointestinal and respiratory tracts, in particular treatment and prevention of urinary tract infections. A doctor's decision is required for the use of this drug.  此藥用於治療呼吸道及腸胃道感染，尤其於尿道炎治療和預防。選用此藥需經醫生決定。
Tromantadine; its salts (曲金剛胺;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat infections of the skin and mucous membranes caused by herpes. Medical diagnosis is required for the use of this drug.  此藥用於治療由疱疹病毒引致的皮膚及黏膜感染。選用此藥需經醫生斷症適用。
Urokinase (尿激酶)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used in the management of blood clotting disorders, including deep-vein thrombosis and acute heart attacks. Medical diagnosis and monitoring are required for the use of this drug.  此藥用於血液凝固疾病的療理，包括深層血栓性靜脈炎及急性心肌栓塞。選用此藥需經醫生斷症及觀察。