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仿單標籤粘貼表

產品名稱	麻妥儂注射液	申請廠商	歐嘉隆股份有限公司

96. 5. 15

衛生署給證號碼	衛署藥輸	字第	019616	號

衛生署藥政處 (15)

RA 8710 OS S3 (REF 3.0)

麻妥儂®注射液

Pavulon® 4 mg = 2 ml　　衛署藥輸字第 019616 號

1. 品名

麻妥儂注射液。

2. 組成份及含量

每毫升的麻妥儂含 2 毫克的 pancuronium bromide，完整的賦型劑組成請見 6.1 節。

3. 劑型

溶液注射劑。

4. 臨床特性

4.1 適應症

本品作全身麻醉的輔佐藥，以幫助氣管內插管及提供中度及長時間手術時的骨骼肌鬆弛狀態。

4.2 使用劑量與投與途徑

劑量

與所有其他神經肌肉阻斷劑相同，Pavulon 須由熟悉這類藥物的作用與用法的熟練醫師給藥或在其嚴密監測下始能給予。

與其他所有神經肌肉阻斷劑一樣，Pavulon 的劑量應依個別患者而定。決定用藥劑量時，應把麻醉方式，預定手術時間、麻醉前或麻醉時所使用的其他藥物可能產生的交互作用與及患者的狀況等納入考量。並建議使用適當的神經肌肉監測方法，來偵測神經肌肉的阻斷及恢復情形。

吸入性麻醉劑會加強 Pavulon 的神經肌肉的阻斷作用，然而僅在吸入性麻醉劑達到足以產生交互作用的組織濃度時才會在麻醉過程中產生臨床上有意義的增強作用。可藉著投予在較低的頻率下以較小的維持劑量來調整 Pavulon 的劑量 (請參考 4.5 節)。

在成人病患方面，下述劑量可作爲於中到長時間手術過程中，氣管內插管與肌肉鬆弛所建議劑量的一般參考。

氣管插管

在常見的麻醉的標準插管劑量爲每公斤體重 0.08 至 0.1 毫克的 pancuronium bromide。靜脈注射每公斤體重 0.1 毫克 pancuronium bromide，臨床上可被接受的插管狀況設定爲經靜脈注射每公斤體重靜脈注射每公斤體重 0.1 毫克 pancuronium bromide 後的 90 至 120 秒之間與每公斤 0.08 毫克的 pancuronium bromide 後的 120 至 180 秒之間。從給予每公斤體重 0.08 毫克的 pancuronium bromide 到恢復至對照抽動高度的 25%的時間約爲 75 分鐘，而給予每公斤體重 0.1 毫克的 pancuronium bromide 則需時約 100 分鐘。

Pavulon 的維持肌肉鬆弛劑量

推薦劑量爲每公斤體重 0.01 至 0.02 毫克的 pancuronium bromide。爲減低積蓄作用，建議在擊動高度至少已恢復至對照數值之 25%才投予 Pavulon。

以 suxamethonium 插管後之手術過程使用 Pavulon 的劑量

推薦劑量爲每公斤體重 0.04 至 0.06 毫克的 pancuronium bromide，使用這些劑量下，由靜脈注射至恢復至對照擊動高度的 25%約須 22 至 35 分鐘，視所投予的 suxamethonium 劑量而定。Pavulon 應延至 suxamethonium 所產生的神經肌肉阻斷藥效消失後才投予。

老年患者之劑量

可以使用和年輕成人相同的插管和維持劑量 (分別是 0.08-0.1 mg/kg 和 0.01-0.02 mg/kg)，但是因爲藥物動力學機轉的變化，在老年病患的作用期間會比年輕人的長。

小兒科病患的劑量

臨床研究顯示新生兒（0~1 個月）及嬰兒（1~12 個月）的劑量所需與成年人相當。因對非去極化神經肌肉阻斷劑不同的敏感度，建議在新生兒給予以每公斤體重 0.01 至 0.02 毫克的 pancuronium bromide 爲初始試用劑量。根據研究報告顯示兒童（1~14 歲）則需較高的劑量(大約 25%)。

過重及肥胖病患

當使用在過重與肥胖患者（定義爲體重超過理想體重的 30%或以上的病患）應將其理想體重列爲考慮而減低劑量。

給藥方法

Pavulon 僅供靜脈注射，最好一次注入輸注中之點滴管中。

4.3 禁忌症

先前曾對 Pancuronium 或溴離子產生過敏反應或者對 Pavulon 的賦形劑的任一成份敏感者。

4.4 警告及注意事項

因 Pavulon 會使呼吸肌肉的麻痺，接受此藥的患者，應以呼吸換氣輔助，直至其恢復至足夠的自發性呼吸爲止。

和其他神經肌肉鬆弛劑一樣，Pavulon 也曾被報導過有殘餘箭毒作用。爲了避免殘餘箭毒作用造成的併發症，建議只在病患已經從神經肌肉阻斷充分恢復之後才拔管。其他可能在開刀完拔管後導致殘餘箭毒作用的因素(例如藥物相互作用或者病患的狀況)也都應該被考慮。假如並未以標準臨床操作的一部份使用時，應該考慮使用反轉藥物，特別是對那些好像可能發生殘餘箭毒症狀的病患。

Pavulon® 4mg=2ml

1. NAME OF THE MEDICINAL PRODUCT

Pavulon® 4 mg=2 ml, solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Pavulon contains 2 mg pancuronium bromide.
For a full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Pavulon is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgical procedures of intermediate and long duration.

4.2 Posology and method of administration

Dosage

Like other neuromuscular blocking agents, Pavulon should only be administered by or under supervision of experienced clinicians who are familiar with the action and use of these drugs.

As is the case for all other neuromuscular blocking agents, the dosage of Pavulon should be individualized in each patient. The method of anesthesia, expected duration of surgery, possible interaction with other drugs that are administered before or during anesthesia and condition of the patient should be taken into account when determining the dose. The use of an appropriate neuromuscular monitoring technique is recommended for monitoring neuromuscular block and recovery.

Inhalational anesthetics do potentiate the neuromuscular blocking effects of Pavulon. This potentiation however, becomes clinically relevant in the course of anesthesia, when the volatile agents have reached the tissue concentrations required for this interaction. Consequently, adjustments with Pavulon should be made by administering smaller maintenance doses at less

frequent intervals during procedures under inhalational anesthesia (see section 4.5).

In adult patients the following dosage recommendations may serve as a general guideline for tracheal intubation and muscle relaxation for intermediate to long lasting surgical procedures.

Tracheal intubation

The standard intubating dose during routine anesthesia is 0.08 to 0.1 mg pancuronium bromide per kg bodyweight. Clinically acceptable intubation conditions are established within 90 to 120 seconds after intravenous injection of a dose of 0.1 mg pancuronium bromide per kg bodyweight and within 120 to 180 seconds after a dose of 0.08 mg pancuronium bromide per kg bodyweight. Time from intravenous administration to 25 % recovery of control twitch height is approximately 75 minutes after a dose of 0.08 mg pancuronium bromide per kg bodyweight and approximately 100 minutes after a dose of 0.1 mg pancuronium bromide per kg bodyweight.

Doses of Pavulon for maintenance of muscle relaxation

The recommended maintenance dose is 0.01 to 0.02 mg pancuronium bromide per kg bodyweight. In order to limit cumulative effects, it is recommended to administer maintenance doses of Pavulon only when the twitch height has recovered to at least 25% of its control value.

Doses of Pavulon for surgical procedures after intubation with suxamethonium

The recommended dose is 0.04 to 0.06 mg pancuronium bromide per kg bodyweight. With these doses, the time from intravenous administration to 25% recovery of control twitch height is approximately 22 to 35 minutes, depending on the dose of suxamethonium administered. The administration of Pavulon should be delayed until the patient has clinically recovered from the neuromuscular block induced by suxamethonium.

Dose in elder patients

The same intubation and maintenance doses as for younger adults (0.08-0.1mg/kg and 0.01-0.02mg/kg, respectively) can be used. However, the durartion of action is prolonged in elderly compared to younger subjects due to changes in pharmacokinetic mechanisms.

Dosing in pediatric patients

Clinical studies have demonstrated that the dose requirements for neonates (0-1 month) and infants (1-12 months) are comparable to adults. Due to a variable sensitivity to non-depolarizing neuromuscular blocking agents, it is recommended to use an initial test dose of 0.01-0.02 mg/kg in neonates. Children (1-14 years) are reported to require a higher dose (approximately 25%).

Dosing in overweight and obese patients

When used in overweight or obese patients (defined as patients with a body weight of 30% or more above the ideal body weight) doses should be reduced taking into account the ideal body weight.

Administration

Pavulon is administered intravenously only, preferably as a bolus injection into the line of a running infusion.

Like other neuromuscular blocking agents, Pavulon should only be administered by or under supervision of experienced clinicians who are familiar with the action and use of these drugs.