Midazolam

【IMID】Midatin® 5mg/1mL/Amp *ATC Code：N05CD08*

中 文 名： 美得定注射液 «南光化學»

適 應 症： 知覺鎮靜、急救加護病房鎮靜、麻醉誘導及維持、手術前給藥。

【ODORM】Dormicum® 7.5mg/Tab *ATC Code：N05CD08*

中 文 名： 導眠靜膜衣錠 «Roche»

適 應 症： 睡眠障礙和各類不眠症、外科、診斷過程前的鎮靜給藥。

藥理分類： **Benzodiazepine, Anticonvulsant.**

用法用量： **Administration:**

Tablet: orally, taken without regard to meals.

Parenteral:

For IM use, inject deep in a large muscle mass.

For IV use, administer over at least 2 mins and allow an additional 2 or more minutes to fully evaluate the sedative effect.

Indications and Dose regimen:

Adults:

－Preoperative Sedation, Anxiolysis, and Anterograde Amnesia:

IM, 70-80 mcg/kg (about 5 mg) administered approximately 30-60 minutes prior to surgery. If administered concomitantly with an opiate agonist or other CNS depressant, the midazolam dosage must be individualized and reduced.

－Procedural Sedation:

IV, initial dose of ≦ 2.5 mg in healthy adults < 60 yrs; some patients may respond to as little as 1 mg. Total dose of ≦ 5 mg generally is adequate.

－Induction and Maintenance of Anesthesia:

Without Opiate Premedication:

Initial dose of 300-350 mcg/kg administered IV over 20-30 seconds in patients < 55 yrs; allow approximately 2 min for clinical effect. Alternatively, some clinicians recommend an initial dose of 200 mcg/kg.

With Opiate or Sedative Premedication:

Initial dose of 150-350 mcg/kg IV as an induction dose in patients < 55 yrs. Usual induction dose is 250 mcg/kg administered IV over 20-30 seconds; allow approximately 2 minutes for clinical effects.

－Sedation in Critical-care Settings

If a loading dose is necessary to initiate sedation rapidly, 10-50 mcg/kg (approx. 0.5-4mg) administer-ed slowly or infused over several minutes. Repeat this dose at 10- to 15-minute intervals until adequ- ate sedation is achieved. Usual initial infusion rate for maintenance of sedation is 20-100 mcg/kg/hr (approx.1-7 mg/hr). Higher loading doses or maintenance infusion rates occasionally may be required.

－**Insomnia:** 7.5-15 mg ORALLY at bedtime.

Pediatric Patients:

－Preoperative Sedation, Anxiolysis, and Antero- grade Amnesia / Procedural Sedation :

Oral: 6 months to 16 yrs

250-500 mcg/kg as a single dose, MAX 20 mg.

IV:

6 months to 5 yrs:

Initially, 50-100 mcg/kg IV over 2-3 minutes; total dose up to 600 mcg/kg

may be necessary; total dose usually does not exceed 6 mg.

6 to 12 yrs:

Initially, 25-50 mcg/kg IV over 2-3 minutes; total dose up to 400 mcg/kg may be needed; total dose usually does not exceed 10 mg.

12 to 16 yrs:

Dose as adults; some patients in this age range will require higher than recommended adult doses; total dose usually does not exceed 10 mg.

IM: 1 month of age

100-150 mcg/kg IM (up to 500 mcg/kg IM for more anxious patients); total dose usually does not exceed 10 mg. If given in combination with an opioid, reduce dose of both agents.

－Sedation in Critical-care Settings

Neonates

IV loading doses should not be used in neonates; rather, the infusion may be administered more rapidly for the first several hours to establish therapeutic plasma drug concentrations. Carefully and frequently reassess the rate of infusion to administer the lowest possible effective dose and reduce the potential for drug accumulation and potential for adverse effects related to the presence of benzyl alcohol.

Preterm neonates (< 32 weeks'gestation): Initially, 30 mcg/kg/hr (0.5 mcg/kg/min). Term neonates (≧ 32 weeks'gestation): Initially, 60 mcg/kg/hr (1 mcg/kg/min).

Non-neonatal Pediatric Patients (Intubated)

Initially, 50-200 mcg/kg as a loading dose, followed by a continuous IV infusion initiated at a rate of 60-120 mcg/kg/hr (1-2 mcg/kg/min) to maintain the clinical effect.

不良反應： 呼吸抑制、嗜睡、鎮靜、運動失調。

交互作用：

- **Azelastine (Nasal), Flunarizine, Buprenorphine, CNS depressants, Opioid Agonists, Alcohol**: ↑ the CNS depressant effect.
- **Itraconazole,** Paxlovid, Clarithromycin, Itraconazole, MiFEPRIStone, Voriconazole, Aprepitant, DilTIAZem, Dronedarone, Erythromycin, Fluconazole, Grapefruit Juice, Imatinib, Ribociclib, Verapamil, Fusidic Acid (Systemic): ↑ the serum concentration of Midazolam.

配伍禁忌： 1.不可與鹼性注射液混合，midazolam 會在 sodium bicarbonate 內發生沉澱。
2.不可以 Macrodex 6%之 Dextrose 溶液稀釋 Dormicum®安瓿溶液。

注意事項： 1.錠劑：空腹或與食物一起服用皆可。 2.服藥期間應避免心開車或操作危險機械。3.服用本品可能出現夢遊行為，如開車、打電話及準備與食用食物。

懷 孕 期： 1.尚無足夠的數據以評估 midazolam 用於懷孕之安全性。除非沒有更安全的代替方法，否則懷孕期間應避免使用 benzodiazepines。
2.在懷孕的最後三個月給予 midazolam 或分娩期間給予高劑量，有報告指出胎兒的心跳不規則、新生 兒出現肌張力過弱、吸吮力不足、體溫過低和中度呼吸抑制等作用。
3.母體若於懷孕後期階段長期接受 benzodiazepines，嬰兒可能會發展出生理依賴性，且在產後期間也可能發展出戒斷症狀的危險性。

授 乳 期： Midazolam 會少量分泌於乳汁中，所以建議授乳母親應在服用 midazolam 24 小時內停止授乳。

相容輸注液： D5W、NS。(混合濃度為每 100-1000ml 的輸注溶液中，含 15mg midazolam。稀釋後室溫可保存 24 小時或冷藏維持 3 天)。

儲　　存： Dormicum® 5 mg/1mL/Amp 室溫避光儲存；有效期限內藥品之沉澱現象在室溫下搖晃會重新溶解。