Fentanyl Intravenous - Standard Concentration

Newborn use only

2025

Alert	S8 High risk medicine. Must be stored and handled according to local S8 drug policy. High risk of causing significant patient harm when used in error.
Indication	Analgesia. Sedation.
Action	Binds to specific G protein-coupled opioid receptors that are in the brain and spinal cord regions involved in the transmission and modulation of pain.
Drug type	Opioid analgesic agent.
Trade name	B. Braun Fentanyl, DBL Fentanyl, Fentanyl GH, Fentanyl Juno, Fentanyl Medsurge, Fentanyl-hameln, Sublimaze
Presentation	500 microgram/10 mL ampoule; 100 microgram/2 mL ampoule
Dose	**Bolus/loading dose** 0.5–4 microgram/kg/dose over 3–5 minutes – may be required every 2–4 hours. **Continuous IV Infusion** 1–5 microgram/kg/hour. General starting dose: 1 microgram/kg/hour. Titrate using a validated pain score. **Pre-medication for intubation** 2–4 microgram/kg bolus. Wait at least 3 minutes for onset of action after giving the dose.
Dose adjustment	Therapeutic hypothermia – Insufficient evidence to recommend any dose adjustment. [21, 24] ECMO - Higher doses may be needed for procedural analgesia [22,24] Hepatic impairment - May not need any change [23] Renal impairment - May not need any change [20]
Route	IV
Preparation	**Note: Refer to Appendix for tables to assist with concentration selection.** **Weight suggestions for infusion concentrations below are a guide only. Clinicians may choose infusion concentration different to the suggested based on expected dose and the corresponding 24-hour fluid volumes**

Infant weight	<1 kg	1 to <3 kg	≥3 kg
Suggested fentanyl concentration	**4 microgram/mL**	**10 microgram/mL**	**20 microgram/mL**
1 microgram/kg/hour is equal to	0.25 mL/kg/hour	0.1 mL/kg/hour	0.05 mL/kg/hour
IV bolus of 1 microgram/kg is equal to	0.25 mL/kg	0.1 mL/kg	0.05 mL/kg

NOTE: Use the smallest volume syringe available/suitable for drawing up the drug for the preparation. (e.g. for <1 mL draw up – use 1 mL syringe).

20mL Syringe

Step 1: Draw up fentanyl and add compatible fluid* as per table below to make a final volume of 20 mL:

Fentanyl concentration	**4 microgram/mL**	**10 microgram/mL**	**20 microgram/mL**
Volume of fentanyl (50 microgram/mL)	1.6 mL (80 microgram)	4 mL (200 microgram)	8 mL (400 microgram)
Volume of compatible fluid*	18.4 mL	16 mL	12 mL
Total volume	20 mL	20 mL	20 mL

*Compatible fluid: glucose 5% or sodium chloride 0.9%

<table>
<tr><td></td><td>

50mL Syringe

Step 1: Draw up fentanyl and add compatible fluid* as per table below to make a final volume of 50 mL:

Fentanyl concentration	4 microgram/mL	10 microgram/mL	20 microgram/mL
Volume of fentanyl (50 microgram/mL)	4 mL (200 microgram)	10 mL (500 microgram)	20 mL (1000 microgram)
Volume of compatible fluid*	46 mL	40 mL	30 mL
Total volume	50 mL	50 mL	50 mL

*Compatible fluid: glucose 5% or sodium chloride 0.9%

IV BOLUS/LOADING DOSE
Draw up 0.4 mL (20 microgram) of fentanyl and add 9.6 mL of sodium chloride 0.9% to make a final volume of 10 mL with a concentration of 2 microgram/mL.
Note: If a continuous infusion is running, bolus doses/loading dose can be calculated and given from the continuous infusion solution.

PRE-MEDICATION FOR INTUBATION
As above for IV bolus.
</td></tr>
<tr><td>Administration</td><td>Slow IV bolus over 3−5 minutes
Continuous IV infusion</td></tr>
<tr><td>Monitoring</td><td>Hepatic and renal function.
Full cardiorespiratory monitoring is required.
Monitor for urinary retention.</td></tr>
<tr><td>Contraindications</td><td>Known hypersensitivity to fentanyl.</td></tr>
<tr><td>Precautions</td><td>Tolerance can occur with use >5−7 days.
Withdrawal has been reported in patients who have received continuous infusions for >5days.
Chest wall rigidity can occur at any dose.
May cause respiratory depression.
May cause urinary retention.
May decrease intestinal motility.</td></tr>
<tr><td>Drug interactions</td><td>Ketoconazole and erythromycin are potent inhibitors of fentanyl metabolism.
When given in combination with amiodarone can cause profound bradycardia, sinus arrest and hypotension.</td></tr>
<tr><td>Adverse reactions</td><td>Nausea and/or vomiting
Muscle/chest wall rigidity (usually naloxone responsive). Naloxone 20-40 micrograms/kg reversed muscle rigidity immediately allowing resuscitation in a case series of 8 patients. (11)
At high doses can cause neuro-excitation and rarely seizure like activity/myoclonic movements.
Respiratory depression.
Bradycardia (usually atropine responsive).
Urinary retention.</td></tr>
<tr><td>Overdose</td><td>AUSTRALIA: Contact the Poisons Information Centre on 13 11 26 for management

NEW ZEALAND: Contact the National Poisons Centre on 0800 764 766 for management</td></tr>
<tr><td>Compatibility</td><td>Fluids: Sodium chloride 0.9%, glucose 5%
Amino acids at Y site: Yes

Lipid emulsion at Y site: Yes

Y-site (16): acyclovir, adrenaline (epinephrine), alfentanil, alprostadil, amikacin, amiODAROne, amphotericin B lipid complex, amphotericin B liposome, ascorbic acid, atenolol, atropine, azATHIOPRINE, aztreonam, caffeine citrate, calcium chloride, calcium gluconate, caspofungin, cefALOTIN, cefaZOLin, cefOTAXIME, cefOXITIN, cefTAZIDIME, cefTRIAXONE, ciclosPORIN, clindamycin, clonidine, cloxacillin, dexAMETHASOne, dexMEDETOMIDine, digoxin, diltiazem, dobutamine, dopamine, doxycycline, enalaprilat, epoeitin alfa, ERYthromycin lactobionate, flucONAZOLe, fluorouracil, folic acid (sodium salt), fosphenytoin, furosemide, ganciclovir, gentamicin, glycopyrrolate, heparin, hydrocortisone sodium succinate, imipenem-cilastatin, indomethacin, insulin, labetolol, lidocaine, linEZOLID, LORazepam, magnesium sulfate, meropenem-vaborbactam, methylprednisolone sodium succinate, metronidazole, midazolam, milrinone, morphine</td></tr>
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	sulfate, naloxone, netilmicin, nitroglycerin, nitroprusside sodium, noradrenaline (norepinephrine), octreotide, oxacillin, pamidronate, pancuronium, papaverine, paracetamol (acetaminophen), penicillin G sodium, penicillin G potassium, pentobarbital, phenobarbital, phenylephrine, piperacillin, piperacillin-tazobactam, potassium chloride, potassium acetate, propOFol, propRANOLol, protamine, pyridoxine, ranitidine, remifentanil, rocuronium, sodium acetate, sodium bicarbonate, streptokinase, succinylcholine, thiamine, thiopental, ticarcillin, tobramycin, tolazoline, urokinase, vancomycin, vasopressin, vecuronium, verapamil. **Variable compatibility:** amphotericin B conventional colloidal, ampicillin, aziTHROMYCIN, DIAzepam, hydralazine.
Incompatibility	**Fluids:** No information. **Y-site [16]:** diazoxide, pantoprazole, phenytoin, sulfamethoxazole-trimethoprim.
Stability	Continuous IV infusion should be used within 24 hours
Storage	Ampoule: Store below 25°C. Protect from light. Discard remainder after use (in line with S8 drug legislation). Store in Dangerous Drug (DD) safe and record use in DD register.
Excipients	B.Braun – sodium chloride, water for injections DBL Fentanyl – Hydrochloric acid, sodium chloride, sodium hydroxide, water for injections Fentanyl GH – sodium chloride, water for injections, sodium hydroxide Fentayl Juno – sodium chloride, water for injections, sodium hydroxide Fentanyl Medsurge – sodium chloride, sodium hydroxide, water for injections Fentanyl-hameln – sodium chloride, hydrochloric acid, sodium hydroxide, water for injections Sublimaze – sodium chloride, water for injections
Evidence	**Background** Fentanyl is a synthetic opioid analgesic, used in neonates because of rapid analgesia, hemodynamic stability, blocking stress responses and preventing increases in pulmonary vascular resistance. Fentanyl is highly lipophilic, crosses the blood brain barrier rapidly, accumulates in fatty tissues, and causes less histamine release than morphine. Fentanyl has greater analgesic potency, a faster onset and shorter duration of action than morphine. Tolerance to fentanyl develops more rapidly than to morphine, requiring the escalation of doses during prolonged administration. [17] **Efficacy** **Analgesia:** Opioids are to be used selectively based on clinical judgment and evaluation of pain indicators, although there are limitations to pain measurement in newborns (1) (LOE 1 GOR B). Continuous infusion of fentanyl 1.1 micrograms/kg/hour (range 0.5-2.0) in the post-operative period achieves acceptable pain control but there may be increased need for ventilator support (2) (LOE II, GOR C). **Premedication for intubation:** Combinations including fentanyl reported in several small trials (3-6) and a cohort study (7). Fentanyl 2 microgram/kg - succinylcholine 2 mg/kg - atropine 20 microgram/kg combination was reported to result in better intubation condition than remifentanil (3 microgram/kg) - atropine 20 microgram/kg in newborn infants. Chest wall rigidity was reported in both groups (3) [LOE II]. A review concluded, based on current evidence, an optimal protocol for premedication is to administer a vagolytic (intravenous atropine), a rapid-acting analgesic (IV fentanyl 3 µg/kg to 5 µg/kg; slow infusion) and a short-duration muscle relaxant (IV succinylcholine) (8). [LOE III-2 GOR C] **Analgesia/sedation for mechanical ventilation:** A short course of low dose fentanyl by infusion reduces behavioural sedation scores, O2 desaturations and neuroendocrine stress responses in preterm ventilated infants (9) (LOE II, GOR B). (2) In very preterm infants on mechanical ventilation, continuous fentanyl infusion plus boluses of fentanyl reduces acute pain and increases side effects but does not reduce prolonged pain compared with boluses of fentanyl alone (10) (LOE II GOR B). **Fentanyl versus morphine conversion factor:** Exact conversion factor for converting fentanyl to morphine remains unknown with literature reporting up to 100:1 for a variety of age groups. A more conservative conversion factor of 10-20 has been found to be effective for neonates. (18,19) **Fentanyl versus morphine analgesia:** In a randomized double-blind trial, neonates were allocated to receive a continuous infusion of fentanyl (10.5 microgram/kg over a 1-hour period followed by 1.5 microgram/kg/hr) or morphine (140 microgram/kg over a 1-hour period followed by 20 microgram/kg/hr) for at least 24 hours. The analgesic effect was similar in both groups. Decreased gastrointestinal motility was less frequent in the fentanyl group (23% vs 47%, P < .01).(19) **Safety**

	Respiratory depression occurs when anaesthetic doses (greater than 5 microgram/kg/min) are used and may also occur unexpectedly because of redistribution. Chest wall rigidity has occurred in 4% of neonates who received doses of 2.2 to 6.5 microgram/kg, occasionally associated with laryngospasm (11) (LOE IV GOR D). This was reversible with administration of naloxone. When controlling for other variables, the cumulative fentanyl dose did not correlate with neurodevelopmental outcomes in very low birth weight infants (12) (LOE III GOR C). Tolerance may develop to analgesic doses (13). Significant withdrawal symptoms have been reported in patients treated with continuous infusion and was universal for infants receiving >2.5 mg or >9 days infusion (14). [LOE IV GOR D] **Pharmacokinetics** Fentanyl is metabolised in the liver (CYP3A4) and excreted in the urine. Half-life was 9.5 hours (range 5.7 to 12.7 hours). There is significant correlation between postnatal age and total body clearance (15). Fentanyl clearance is very low during the first days of life in very preterm infants which can lead to accumulation of the drug. Clearance increases with gestational age as well as with postnatal age. Bodyweight-based fentanyl dose needs to be reduced during the first days of life to achieve comparable exposure across all preterm infants. [25]
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Appendix

Infusion tables to assist with concentration selection

Table 1: Infusion rates when using fentanyl concentration **4 microgram/mL**
(suggested weight <1 kg)

Rate (mL/hr)	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
Weight (kg)	**Approximate microgram/kg/hour**									
0.5	0.8	1.6	2.4	3.2	4.0	4.8	5.6	6.4	7.2	8
1	0.4	0.8	1.2	1.6	2.0	2.4	2.8	3.2	3.6	4
1.5	0.3	0.5	0.8	1.1	1.3	1.6	1.9	2.1	2.4	2.7
2	0.2	0.4	0.6	0.8	1	1.2	1.4	1.6	1.8	2
2.5	0.2	0.3	0.5	0.6	0.8	1	1.1	1.3	1.4	1.6
3	0.1	0.3	0.4	0.5	0.7	0.8	0.9	1.1	1.2	1.3
3.5	0.1	0.2	0.3	0.5	0.6	0.7	0.8	0.9	1	1.1
4	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
4.5	0.1	0.2	0.3	0.4	0.4	0.5	0.6	0.7	0.8	0.9
5	0.1	0.2	0.2	0.3	0.4	0.5	0.6	0.6	0.7	0.8

Table 2: Infusion rates when using fentanyl concentration **10 microgram/mL**
(suggested weight 1 to <3kg)

Rate (mL/hr)	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
Weight (kg)	**Approximate microgram/kg/hour**									
0.5	2	4	6	8	10	12	14	16	18	20
1	1	2	3	4	5	6	7	8	9	10
1.5	0.7	1.3	2	2.7	3.3	4	4.7	5.3	6	6.7
2	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5
2.5	0.4	0.8	1.2	1.6	2	2.4	2.8	3.2	3.6	4
3	0.3	0.7	1	1.3	1.7	2	2.3	2.7	3	3.3
3.5	0.3	0.6	0.9	1.1	1.4	1.7	2	2.3	2.6	2.9
4	0.3	0.5	0.8	1	1.3	1.5	1.8	2	2.3	2.5
4.5	0.2	0.4	0.7	0.9	1.1	1.3	1.6	1.8	2	2.2
5	0.2	0.4	0.6	0.8	1	1.2	1.4	1.6	1.8	2

Table 3: Infusion rates when using fentanyl concentration **20 microgram/mL**
(suggested weight ≥3kg)

Rate (mL/hr)	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
Weight (kg)	**Approximate microgram/kg/hour**									
0.5	4	8	12	16	20	24	28	32	36	40
1	2	4	6	8	10	12	14	16	18	20
1.5	1.3	2.7	4	5.3	6.7	8	9.3	10.7	12	13.3
2	1	2	3	4	5	6	7	8	9	10
2.5	0.8	1.6	2.4	3.2	4	4.8	5.6	6.4	7.2	8
3	0.7	1.3	2	2.7	3.3	4	4.7	5.3	6	6.7
3.5	0.6	1.1	1.7	2.3	2.9	3.4	4	4.6	5.1	5.7
4	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5
4.5	0.4	0.9	1.3	1.8	2.2	2.7	3.1	3.6	4	4.4
5	0.4	0.8	1.2	1.6	2	2.4	2.8	3.2	3.6	4

	$\text{Dose (microgram/kg/hour)} = \frac{\text{Rate (mL/hr) x Concentration (microgram/mL)}}{\text{Weight (kg)}}$ $\text{Rate (mL/hr)} = \frac{\text{Dose (microgram/kg/hour) x Weight (kg)}}{\text{Concentration (microgram/mL)}}$

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