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SAFETY DATA SHEET

NAROPIN WITH FENTANYL (Ropivacaine hydrochloride with Fentanyl citrate)

Issue Date:	16th September 2022
Sponsor:	Aspen Pharmacare Australia Pty Ltd
Address:	34-36 Chandos Street, St Leonards, NSW, 2065
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1. IDENTIFICATION OF THE MATERIAL

Product Identifier:

- NAROPIN 0.2% with Fentanyl 200 µg/100mL Ropivacaine hydrochloride 2mg/mL and fentanyl 2 microgram/mL (as citrate) 100mL polybag injection bag.
- NAROPIN 0.2% with Fentanyl 400 µg/100mL Ropivacaine hydrochloride 2mg/mL and fentanyl 4 microgram/mL (as citrate) 100mL polybag infusion bag.
- NAROPIN 0.2% with Fentanyl 400 µg/200mL Ropivacaine hydrochloride 2mg/mL and fentanyl 2 microgram/mL (as citrate) 200mL polybag infusion bag.
- NAROPIN 0.2% with Fentanyl 800 µg/200mL Ropivacaine hydrochloride 2mg/mL and fentanyl 4 microgram/mL (as citrate) 200mL polybag infusion bag.

Other means of identification:

Naropin 0.2% with Fentanyl solution, ropivacaine hydrochloride with fentanyl citrate.

Naropin 2.0 mg/ml + Fentanyl 2 µg/ml

Naropin 2.0 mg/ml + Fentanyl 4 µg/ml

Aspen product code/s:

Australia

07661 - NAROPIN 0.2% with Fentanyl 200 µg/100mL

07662 - NAROPIN 0.2% with Fentanyl 400 µg/100mL

07673 - NAROPIN 0.2% with Fentanyl 400 µg/200mL

07663 - NAROPIN 0.2% with Fentanyl 800 µg/200mL

New Zealand

1049039 - NAROPIN 0.2% with Fentanyl 200 µg/100mL

1068163 - NAROPIN 0.2% with Fentanyl 400 µg/200mL

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Recommended Use: For the management of post-operative pain by epidural infusion for up to 72 hours.

Emergency phone number:

+(61 2) 8436 8300

Poisons Information Centre: 131 126 from anywhere in Australia.

In New Zealand – The national Poisons Centre (telephone 0800 POISON or 0800 764 766)

If you are not sure what to do, contact your medical practitioner or pharmacist.

2. HAZARDS IDENTIFICATION/DATA

Hazard Information:

Specific target organ toxicity – single exposure, Category 3

Harmful if swallowed Category 4

Acute toxicity category 4

Harmful to aquatic life with long lasting effects Category 3

Chronic aquatic toxicity Category 3

Effects on or via lactation

Label Elements, including precautionary statements:

GHS 07- Irritant

GHS 08 Health Hazard

Signal word: Warning

H300 – Fatal is swallowed.

H302 - Harmful if swallowed.

H318 - Causes serious eye damage

H336 - May cause drowsiness or dizziness.

H362 - May cause harm to breast-fed children.

H402 - Harmful to aquatic life.

H412 - Harmful to aquatic life with long lasting effects

Precautionary statement(s):

P264 - Wash skin thoroughly after handling.

P270 - Do not eat, drink, or smoke when using this product.

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Response:

P301 + P312 + P330 if swallowed: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

P305 + P351 + P338 if in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P314 - Get medical advice/ attention if you feel unwell.

Disposal:

P501 - Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification: May cause tingling/numbness in exposed areas (paraesthesia). High atmospheric concentrations may lead to anaesthetic effects.

3. COMPOSITION

Chemical Ingredient	CAS No.	%
Ropivacaine hydrochloride monohydrate	84057-95-4	Low
Fentanyl citrate	990-73-8	Low
Excipients (other ingredients)	Unassigned	Medium
Sodium chloride		
Hydrochloric acid or		
Sodium hydroxide for pH adjustment		
Water for injections		

Concentration Guide: *Low (below 10%)* *Medium (10 to 60%)* *High (above 60%)*

4. FIRST AID MEASURES

In case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In case of Eye: If in eyes: Rinse cautiously with water for at least 10 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation develops and persists, get medical attention.

In case of Ingestion: Rinse mouth thoroughly with water provided person is conscious. Never give anything by mouth to an unconscious

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	person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel. Remove from source of exposure. If signs of toxicity occur, seek medical attention.
Inhalation:	Remove from source of exposure. If inhaled, remove to fresh air and get medical attention if symptoms occur.
Symptoms caused by exposure:	Harmful if swallowed. Inadvertent contact with this product may cause irritation, followed by numbness. May cause tingling/numbness in exposed areas (paraesthesia). May cause excessive watering of the eye (lachrymation). In clinical use, this product produces numbness when injected. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Additional adverse effects have included fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anaemia, back pain, post-operative pain and foetal distress.
Medical attention and special treatment:	Treat symptomatically and supportively. Ropivacaine hydrochloride should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, since the toxic effects of these drugs are additive. Patients treated with class III antiarrhythmic drugs (e.g., amiodarone) should be under close surveillance and ECG monitoring considered, since cardiac effects may be additive.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use Water spray, Alcohol-resistant foam, Dry chemical powder, Carbon dioxide (CO2) as necessary.
Special hazards arising from the substance or mixture:	During fire, gases hazardous to health may be formed. Exposure to combustion products may be a hazard to health.

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	Carbon oxides and Nitrogen oxides (Nox) may be formed.
Advice for firefighters:	As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (See section 8) during removal of spillages. Dispose of spill materials according to the applicable federal, state, or local regulations.
Environmental precautions:	Avoid release to the environment. Avoid dispersal of spilled material into waterways, drains and sewers. Inform the relevant authorities if the product cannot be contained and has caused environmental pollution (sewers, waterways, soil or air).
Methods and materials for containment and cleaning up:	Clear up spillages. Keep the solutions bunded. Contain spills with an inert absorbent material such as soil, sand or dry oil. Absorb spill with inert material, then place in a chemical waste container for disposal. After removal, flush spill area with soap and water to remove trace residue.

7. HANDLING AND STORAGE

Precautions for safe handling:	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice. Take care to prevent spills, waste and minimise release to the environment.
Conditions for safe storage, including any incompatibilities:	Store in a well-ventilated, dry, cool place. Store in original tightly closed container. Store below 30°C. Do not freeze. Protect from light. Store away from incompatible materials. Store in labelled containers. Use appropriate containment to avoid environmental contamination.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters – Exposure standards, biological monitoring:

Occupational exposure limits:

Components	Value type (Form of exposure)	Control parameters
Ropivacaine hydrochloride	0.1 mg/m3	LTEL 8hr TWA
Ropivacaine hydrochloride	1 mg/m3	STEL 15 min.

Engineering controls:

Use feasible engineering controls to minimize exposure to the product. Adequate ventilation, procedural controls and use of personal protection equipment must be used.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Prevent entry into drains.

Personal protective equipment:

Wear PPE. Wear a face shield or other full-face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Eye protection: Safety glasses, face shield or safety goggles is recommended.

Hand protection: Compatible chemical-resistant gloves.

Skin and body protection: Avoid contact with skin. Use Impervious clothing and Personal protective equipment.

Respiratory protection: If adequate local exhaust ventilation is not available use respiratory protection device with filters.

9. PHYSICAL & CHEMICAL PROPERTIES

Description of appearance (Physical form, colour, shape): Injection solution. A clear, colourless, particle free solution.

10. STABILITY AND REACTIVITY

Reactivity: No known reactivity hazard under normal conditions of use, storage and transport.

Chemical stability: Material is stable under standard use and normal storage conditions.

Conditions to avoid Contact with incompatible materials.

Incompatible material and No data available.

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possible hazardous reactions:

Hazardous decomposition products: During thermal decomposition, it may be possible to generate irritating vapours and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

11. TOXICOLOGICAL INFORMATION

Information on routes of exposure:

Inhalation, skin contact, Ingestion and Eye contact.

Inhalation: May cause respiratory irritation.

Ingestion: Harmful if swallowed.

Skin Contact: May cause skin irritation.

Eye Contact: Causes serious eye damage.

Symptoms related to exposure:

Single exposure Exposure routes: Inhalation May cause tingling/numbness in exposed areas (paraesthesia)., High atmospheric concentrations may lead to anaesthetic effects.

Exposure routes: Oral - May produce numbness of the tongue and anaesthetic effects on the stomach.

Repeated exposure: Chronic effects are unlikely.

Sensitisation: No information available.

Carcinogenicity: No information available.

Mutagenicity: No information available.

Target Organ Effects: Based on clinical use, possible target organs include the nervous system, cardiovascular system, and skin.

Reproductive Effects: Pregnancy Category B. Studies conducted with Ropivacaine in rats did not demonstrate an effect on fertility or general reproductive performance over 2 generations.

Ropivacaine was administered subcutaneously to rabbits on gestation days 6-18 at dosages of 1.3, 4.2, or 13 mg/kg/day. Similarly, Ropivacaine was given subcutaneously to rats on gestation days 6-15 at dosages of 5.3, 11 and 26 mg/kg/day. No teratogenic effects were observed in rats or rabbits at the highest dosages tested.

In two pre-natal and post-natal studies, female rats were treated daily from day 15 of gestation to day 20

postpartum with subcutaneous dosages of 5.3, 11 and

26 mg/kg/day. There were no treatment-related effects

on late fetal development, parturition, lactation, neonatal

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viability, or growth of the offspring.

In another study, male rats were dosed daily for 9 weeks before mating and during mating. Females were dosed daily for 2 weeks before mating and then during the mating, pregnancy, and lactation, up to day 42 post

coitus. At a dosage of 23 mg/kg/day, an increased loss

of pups was observed during the first 3 days postpartum. The finding was considered secondary to impaired maternal care due to maternal toxicity.

Fentanyl - Category C

Fentanyl crosses the placenta in humans and has been found in foetal blood at concentrations approximately 40% of those found in maternal blood. The safe use of fentanyl in pregnant women has not been established with respect to possible adverse effects on the foetus or on foetal development. Opioid analgesics used during labour may cause respiratory depression in the newborn infant and should be used only after weighing the needs of the mother against the risk to the foetus. Withdrawal symptoms in newborn infants have been reported with prolonged use of this class of drugs.

Ropivacaine and Fentanyl

Animal studies have not been done to assess the potential for adverse effects on pregnancy or on the foetus when ropivacaine and fentanyl are given in combination.

Use in lactation

Subcutaneous administration of ropivacaine to rats from late gestation to weaning, with estimated systemic exposure (plasma AUC) twice the clinical exposure following a 200 mg epidural dose, did not affect late foetal development, parturition, lactation, neonatal viability, or offspring growth. Ropivacaine and/or its metabolites are excreted into milk in rats, but excretion into human milk has not been investigated.

Small amounts of fentanyl have been detected in breast milk.

Numerical measures of toxicity:

Acute Toxicity: Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and supplier SDS for active ingredients.

Ropivacaine Hydrochloride

Species: Rat Route: Oral Test Type: LD50 Dosage: 56 mg/kg.

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Immediate, delayed and chronic health effects from exposure:	Chronic effects are unlikely. Repeated and/or prolonged contact may cause irritation. Overdose: If you are particularly sensitive to NAROPIN, or the dose is accidentally injected directly into your blood, you may develop problems with your sight, hearing, and get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles.
Exposure levels:	No data available
Interactive effects:	No data available
Data limitations:	No data available

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No information on this formulation.

The following information refers to the active ingredient Ropivacaine hydrochloride. Harmful to aquatic life with long lasting effects.

Aquatic toxicity:

Ingredient	Species	Test Type	Dosage	Duration
Ropivacaine Hydrochloride	Green algae	EC50	59 mg/l	72 hrs
	Daphnia magna	EC50	34 mg/l	48 hrs
	Zebra fish	EC50	38 mg/l	96 hrs
	Microtox test	EC50	>1,000 mg/l	15 mins

Persistence, degradability & Persistence:	Not rapidly biodegradable.
Bioaccumulative potential:	The substance has low potential for bioaccumulation.
Mobility in Soil:	The substance is soluble in water.
Other adverse effects:	No data available.

13. DISPOSAL CONSIDERATIONS

Safe handling and disposal Dispose substance in accordance with prevailing country,

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methods:	federal, state and local regulations. Any NAROPIN with Fentanyl which is not used, and which is left in the container, will be disposed of in a safe manner by your doctor, nurse or pharmacist.
Disposal of any contaminated packaging:	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. Dispose of container and unused contents in accordance with federal, state and local regulations.
Environmental regulations:	No data available. Do not let the product enter into waterways, drains and wastewater.

14. TRANSPORT INFORMATION

UN number:	Not listed as a dangerous goods. Not regulated as a hazardous material.

15. REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product in question:	https://www.nps.org.au/medicine-finder/naropin-with-fentanyl-2-mg-m-l-2-mcg-m-l-epidural-infusion Refer to local government regulations. Product Information (PI) and Consumer Medical Information (CMI) available from TGA website.
Poisons Schedule Number:	(S8) Controlled Drug

16. OTHER INFORMATION

Date of preparation or review:	14th September 2022
Key abbreviations or acronyms used:	CAS No. = Chemical Abstracts Service Number EC50 = Effective concentration 50% of test population LD50 = Lethal Dose to 50% of test population LC50 = Lethal Concentration to 50% of test population TWA = 8-hour Time Weighted Average LTEL = Long-term exposure limit STEL = Short-term exposure limit

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