



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	392512	Parecoxib-AFT parecoxib (as sodium) 40 mg powder for injection vial
ARTG entry for	Medicine Registered	
Sponsor	AFT Pharmaceuticals Pty Ltd	
Postal Address	PO Box 748, North Ryde, Sydney, NSW, 1670 Australia	
ARTG Start Date	2/06/2023	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . Parecoxib-AFT parecoxib (as sodium) 40 mg powder for injection vial

Product Type	Single Medicine Product	Effective Date	5/09/2023 9:56:07 AM
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Permitted Indications
No Permitted Indications included on Record

Indication Requirements
No Indication Requirements included on Record

Standard Indications
No Standard Indications included on Record

Specific Indications
For a single peri-operative dose for the management of post-operative pain

Warnings
See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	24 Months	Store below 30 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
10 vials	(S4) Prescription Only Medicine

Components

1 . Parecoxib-AFT parecoxib (as sodium) 40 mg powder for injection vial

Dosage Form	Injection, powder for
Route of Administration	Intravenous Intramuscular
Visual Identification	Parecoxib-AFT is a white to off-white sterile lyophilised cake or powder in a single use vial

Active Ingredients

parecoxib sodium	42.36 mg
Equivalent: parecoxib	40 mg

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Other Ingredients (Excipients)

dibasic sodium phosphate

phosphoric acid

sodium hydroxide

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