Preparing a Product Information document for a generic medicine

Quality and regulatory expectations

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5 June 2024

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

Welcome

Housekeeping

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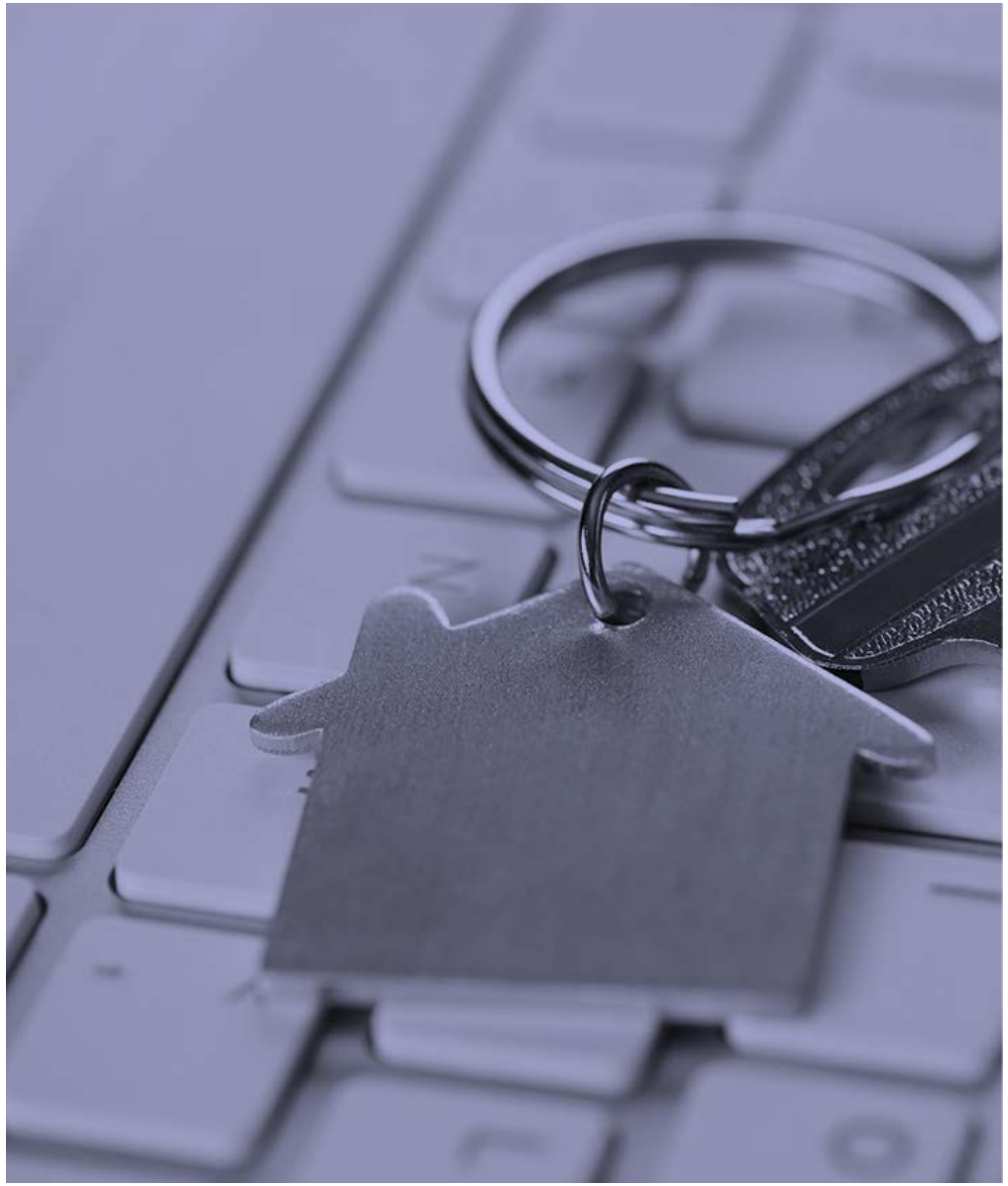

Ask us questions

How to access and use Slido

Through the Slido application in Webex

- Click on the **Apps** icon
- Select **Slido**
- Open the **Q&A** tab to ask questions
- Live Poll (use survey tab when prompted)

Using the QR code

Scan the QR code to access Slido from your mobile device

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Overview

1. Regulatory expectations for PI documents for generic medicines.
2. Frequent formatting issues.
3. Section-by-section overview of PI.
4. Panel discussion.

Product Information (PI)

- Objective information about the quality, safety and efficacy of a medicine.
- Intended to assist doctors, pharmacists and other healthcare professionals in prescribing, dispensing and administering medicines.
- Generic PIs must be based upon the Australian Reference/Innovator PI.
- Must follow the **Approved form for product information in relation to medicine under subsection 7D(1) of the *Therapeutic Goods Act 1989.***
- Better formatted and improved quality PI documents ensures that safety information is clearly conveyed and will reduce the regulatory burden on sponsors and TGA evaluators.

Submission expectations for a generic PI

Milestone 1

The PI **must** be based upon the current PI for the Australian Reference/Innovator product.

The provision of a clean and **annotated PI** is a **mandatory requirement.**

Milestone 3

A core PI with <TRADE NAME> instead of the name of the product - **preferred.**

OR

Individual PIs for each of the proposed trade names –**more onerous for both sides.**

Milestone 5

Individual PI for each proposed tradename with changes made.

Take particular care as differences in length of trade name will affect the formatting of the PI.

VARIATION SUBMISSIONS

- Summary of changes, either listed or tabulated, in the cover letter.
- Updated Section 10 Table of changes.
- For reformatted PIs – appreciated if this is flagged at submission so it can be promptly actioned.
- If a PI covers more than one product, **all products** must be included in the variation Application Form.

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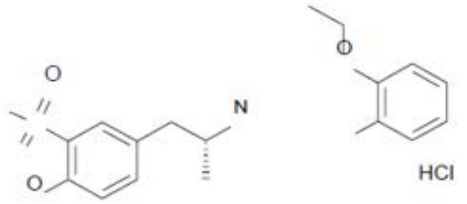
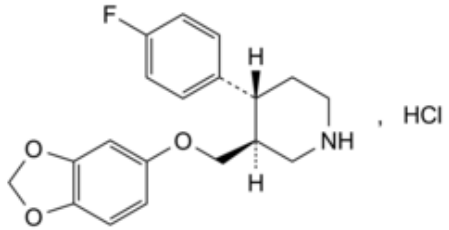
Common formatting issues

Illegible or incorrect chemical structures



X



ü

Quantities and their units are not stated on the same line

Injections should not be repeated more often than every 10 to 15 minutes. A 5 mg intramuscular dose should raise blood pressure for one to two hours. A 0.5 mg intravenous dose should elevate the pressure for about 15 minutes.

X

Injections should not be repeated more often than every 10 to 15 minutes. A 5 mg intramuscular dose should raise blood pressure for one or two hours. A 0.5 mg intravenous dose should elevate the pressure for about 15 minutes.

ü

Common formatting issues

Tables running over more than one page with no column headings on second page

Cardiac disorders				
Hypertension	77 (1.65%)		86 (1.83%)	
Hypotension	244 (5.24%)		238 (5.07%)	
Tachycardia	74 (1.59%)		71 (1.51%)	
Procedural hypotension	47 (1.01%)		34 (0.72%)	
Endocrine disorders				
Hyperglycaemia	43 (0.92%)		53 (1.13%)	

x

	(10 mg od) N = 4657		(40 mg od) N = 4692	
System Organ Class Medical Entity / Preferred Term	**AE**	**ADR**	**AE**	**ADR**
Cardiac disorders				
Hypertension	77 (1.65%)		86 (1.83%)	
Hypotension	244 (5.24%)		238 (5.07%)	
Tachycardia	74 (1.59%)		71 (1.51%)	
Procedural hypotension	47 (1.01%)		34 (0.72%)	

ü

Section headings at bottom of a page with no corresponding text or 2-3 words of a paragraph left hanging at the top of pages
(**lacking context**)

4.3 CONTRAINDICATIONS

[redacted]

Page **2** of 7

x

4.3 **CONTRAINDICATIONS**

Hypersensitivity to any component of this product including sulfites. (see **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**)

ü

SLIDO

Common formatting issues

Information in tables poorly formatted or organised

				VcTD TD VcD VAD n=236 n=238 n=239 n=239
Cardiac toxicity	5 (2.1)	5 (2.1)	nr	nr
Liver toxicity 4 (1.6)	7 (2.9)	nr	nr	
Fatigue (all grades)	nr	nr	68 (28.5)	50 (20.9)
Oedema (all grades)	25 (11)	13 (5)		
Any grade 3 or 4 haematologic adverse	nr	nr	nr	nr **event**
Anaemia	nr	nr	10 (4.2)*	21 (8.8)*
Neutropaenia	nr	nr	12 (5.0)*	24 (10.0)*
Thrombocytopenia	nr	nr	7 (2.9)	3 (1.3)
Thrombosis	nr	nr	4 (1.7)*	13 (5.4)* Discontinued during or after induction 13 (5.5)

x

	VcTD n=236	TD n=238	VcD n=239	VAD n=239
Cardiac toxicity	5 (2.1)	5 (2.1)	nr	nr
Liver toxicity	4 (1.6)	7 (2.9)	nr	nr
Fatigue (all grades)	nr	nr	68 (28.5)	50 (20.9)
Oedema (all grades)	25 (11)	13 (5)		
Any grade 3 or 4 haematologic adverse event	nr	nr	nr	nr
Anaemia	nr	nr	10 (4.2)*	21 (8.8)*
Neutropaenia	nr	nr	12 (5.0)*	24 (10.0)*
Thrombocytopenia	nr	nr	7 (2.9)	3 (1.3)
Thrombosis	nr	nr	4 (1.7)*	13 (5.4)*
Discontinued during or after induction therapy	13 (5.5)	26 (10.9)	44 (18.4)	32 (13.4)
Adverse event leading to death	1 (0.4)	0 (0)	0 (0)*	7 (2.9)*

ü

Inconsistent or incorrect abbreviations for quantities

- µg
- Ml, ‘ml & mL’

x

- ‘µg’ replaced with microgram(s)
- mL is preferred as ‘l’ in some fonts can be confused with ‘1’
- Please be consistent!

ü

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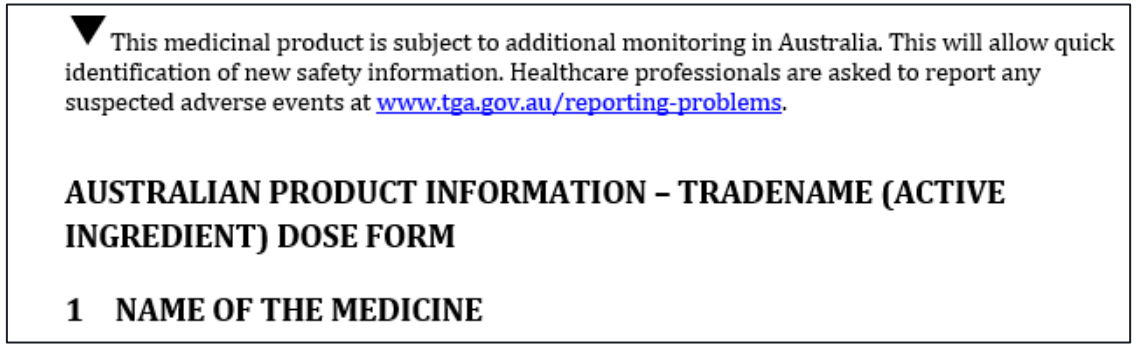
5 June 2024

Black triangle scheme and Black box warnings

- Generic PI must align with Reference PI regarding Black Triangle Scheme or a Black box warning.

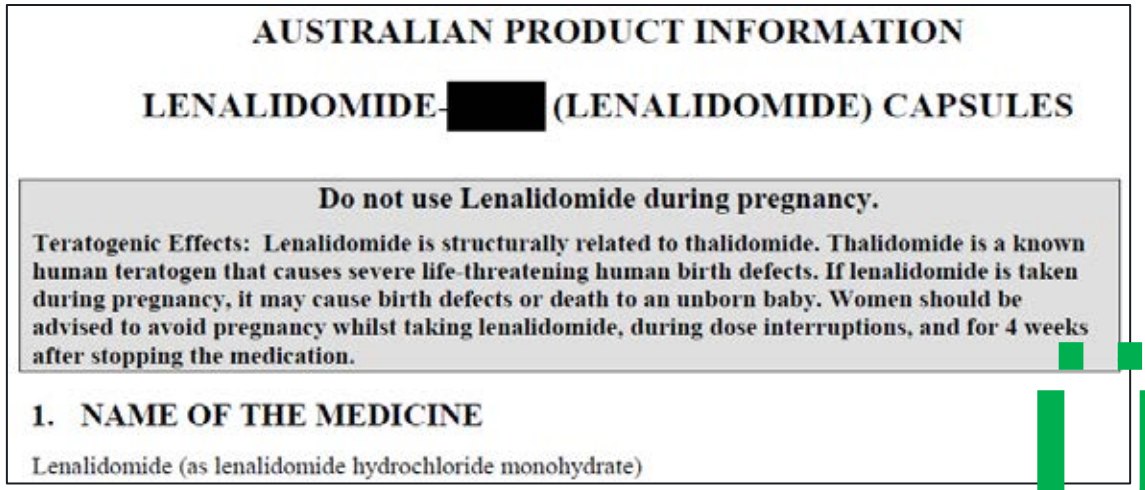
- Preferably located before Section 1 NAME OF THE MEDICINE
  OR
  within Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE – align with Reference PI.



▼This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PRODUCT INFORMATION – TRADENAME (ACTIVE INGREDIENT) DOSE FORM

1 NAME OF THE MEDICINE



AUSTRALIAN PRODUCT INFORMATION

LENALIDOMIDE-[redacted] (LENALIDOMIDE) CAPSULES

Do not use Lenalidomide during pregnancy.

Teratogenic Effects: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Women should be advised to avoid pregnancy whilst taking lenalidomide, during dose interruptions, and for 4 weeks after stopping the medication.

1. NAME OF THE MEDICINE

Lenalidomide (as lenalidomide hydrochloride monohydrate)

PI Title

Active Ingredient

- Should reflect the active moiety as described on label.
- Refer to TGO 91 provisions for name of actives on the labels.

AUSTRALIAN PRODUCT INFORMATION – TRADE NAME (SUGAMMADEX SODIUM) INJECTION

AUSTRALIAN PRODUCT INFORMATION – TRADE NAME (METFORMIN) FILM-COATED TABLET

X

AUSTRALIAN PRODUCT INFORMATION – TRADE NAME (SUGAMMADEX) INJECTION

AUSTRALIAN PRODUCT INFORMATION – TRADE NAME (METFORMIN HYDROCHLORIDE) TABLET

ü

Dosage Form

- Not explicitly stated in Approved Form for providing PI – best practice from safety aspect.
- For tablets, just ‘Tablets’ **not** ‘film-coated / uncoated tablets’.
- But if modified release, use modified release / prolonged release / extended release – **SAME** as Reference PI.

AUSTRALIAN PRODUCT INFORMATION – TRADE NAME (MELATONIN)

X

AUSTRALIAN PRODUCT INFORMATION – TRADE NAME (MELATONIN) CAPSULES and ORAL SOLUTION

ü

Section 1. Name Of The Medicine

AUSTRALIAN APPROVED NAME

- The Australian Approved Name (AAN) of the therapeutically active ingredient or, in the case of a fixed dose combination or composite pack containing multiple therapeutically active ingredients, the AAN of each therapeutically active ingredient should be stated.

ACTIVE INGREDIENT

- Active moiety **AND** salt or solvation form in brackets (don't use abbreviations)

1. NAME OF THE MEDICINE	
Oxycodone and naloxone HCl dihydrate	X
Oxycodone hydrochloride and naloxone hydrochloride (as dihydrate)	ü

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Section 2. Qualitative And Quantitative Composition

GENERAL COMMENTS

- Include a description of the formulation(s) including quantity, portion or strength for each therapeutically active ingredient.
- List of ingredients with known effect, followed by the **mandatory standard text** '**For the full list of excipients, see Section 6.1 List of excipients**'.
- Follow section 11(2) in TGO 91 - Expression of quantity or proportion of active ingredients.
- For multiple strengths, consider the simplest way to express information.

2. QUALITATIVE AND QUANTITATIVE COMPOSITON	
Each TRADE NAME 10 tablet contains 10 mg of sunitinib as sunitinib maleate Each TRADE NAME 20 tablet contains 20 mg of sunitinib as sunitinib maleate	X
TRADE NAME tablets contain 10 mg or 20 mg sunitinib as sunitinib maleate	ü

Section 2. Qualitative And Quantitative Composition

SINGLE USE INJECTION PRODUCTS

- Quantity of the active ingredient **must be stated in the volume of the container** (i.e. vial/ampoule/pre-filled syringe) **NOT** as ‘mg/mL’ quantity .
- List all presentations and corresponding quantitative/qualitative relationships.
- A public consultation regarding electrolyte replacement products and the requirement for the expression of strength in clinically relevant units is now live. TGO 91 will be revised to address this safety concern.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION	
TRADE NAME solution for injection contains Active Substance 10 mg/mL	X
Each vial of TRADE NAME 20 contains 20 mg of Active Substance in 2 mL solution Each vial of TRADE NAME 50 contains 50 mg of Active Substance in 5 mL solution	ü

Section 2. Qualitative And Quantitative Composition

FIXED DOSE COMBINATION (FDC) PRODUCTS

- If two or more actives, list the quantities of the actives in a separate sentence per presentation. e.g.
  - **OXYNALOXY TGA 10/5 contains 10 mg oxycodone hydrochloride and 5 mg of naloxone hydrochloride.**
  - **OXYNALOXY TGA 20/10 contains 20 mg oxycodone hydrochloride and 10 mg of naloxone hydrochloride.**

CLINICALLY RELEVANT PHYSICAL AND CHEMICAL CHARACTERISTICS

- Preferred that this information is relocated to section 6.7 – Physiochemical Properties.

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Section 2. Qualitative And Quantitative Composition

SCHEDULE 1 of TGO 91

- Excipients with known effect **must** be included under section 2 of the PI.
- See TGO 91 Schedule 1 for list of substances, conditions and appropriate wording (**in column 4**).
- Must list sub-excipients of Proprietary Ingredients if they are listed in Schedule 1 of TGO 91.

Column 1 Substance name or Group of substances name	Column 2 Circumstances (if any) and additional requirements (if any)	Column 3 Route of administration	Column 4 Name to be included on the label
aspartame		Oral	aspartame
antibiotics	When the antibiotic is not an active ingredient and is present only as a residual impurity	All	Contains residual 'antibiotic name'
benzoates, including: benzoic acid sodium benzoate		All	benzoates
crustacea and crustacean products (see Note 1), including: crab lobster white shrimp		All	crustacea; or crustacean products
egg, egg products, and products manufactured in eggs including: dried egg yolk		All	egg; or egg products or manufactured in eggs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipients with known effect: Each film-coated tablet of TRADE NAME
- 10 mg contains 45 mg lactose (as monohydrate)
- 40 mg contains 180 mg lactose (as monohydrate)

X

Excipients with known effect: Contains lactose

ü

Excipients with known effect: Contains sodium benzoate

X

Excipients with known effect: Contains benzoates

ü

Section 3. Pharmaceutical Form

Physical appearance of the medicine

Physical description should be consistent with the description in specification

TRADE NAME 300 – A size 0 opaque capsule with orange body and white cap with ‘TN300’ printed in black ink on the body and ‘P’ on the cap.

yellow, oval, film-coated tablets, 10 mm by 5 mm, debossed “KT” on one side and scored on the other side.

[redacted] are a rigid, aluminium, container fitted with a metered dose valve, containing a white homogeneous suspension, fitted to a plastic actuator with a white coloured body and pink coloured cap, with a dose indicator.

ü

If the product is reconstituted, include information on the appearance of the product before AND after reconstitution

White to off-white powder. When reconstituted, yields a colourless solution free of visible particles.

ü

Physical appearance of the drug substance

White to off white powder (**when the product is a solution for injection**).

X

Preparing a Product Information document for a generic medicine

Quality and regulatory expectations

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Section 4. Clinical Particulars

- Generic PIs must be generated from the currently approved version of the Australian reference product PI, to ensure equivalent safety information.

- Clearly identify and justify all differences between the Australian reference product PI and the generic PI, other than the trade name and the sponsor’s details, on the annotated PI.

4.1 Therapeutic Indications

- For new generic products, the indications should be identical to Australian reference product.

Section 4. Clinical Particulars

4.2 Dose And Method Of Administration

- Information relating to preparation and administration must be specific to the generic product and be supported by appropriate quality data.

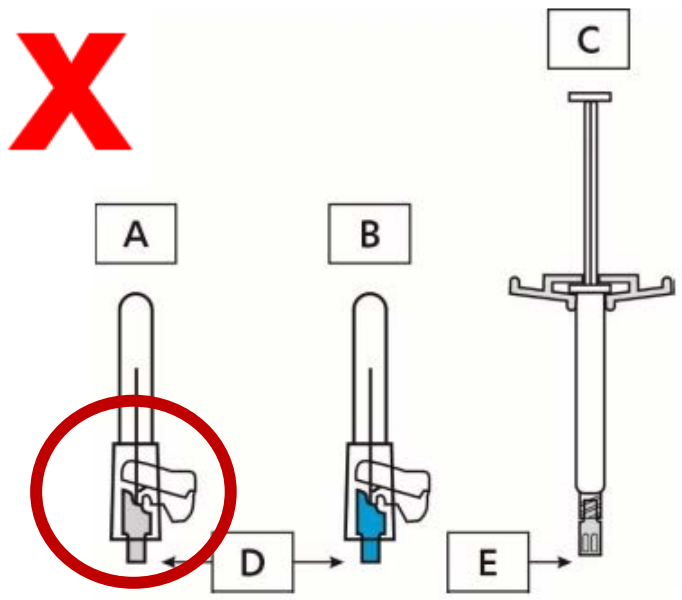
- This may mean that information within 4.2 does not directly align with the reference PI.

  - **Dilution, compatibility or in-use stability information**
  - **Modification of capsules/tablets for administration via enteral tubing or with applesauce/yoghurt**
  - **Different excipients, which may affect reconstitution instructions for injections**
  - **Differences in overage, resulting in different dilution/ reconstitution volumes for injections**
  - **Presentation differences**

Section 4. Clinical Particulars

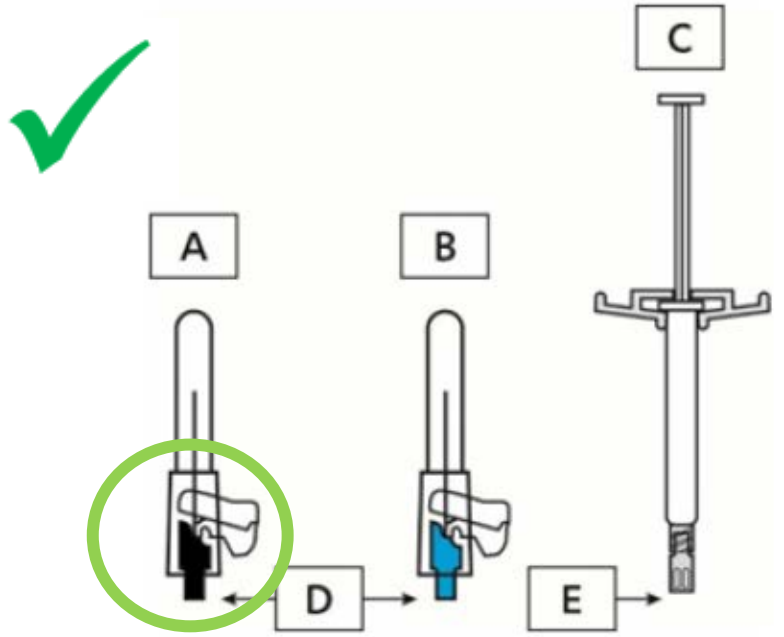
4.2 Dose And Method Of Administration

Image copied from reference PI into generic PI



A-22Gx1½" Gray hub; B-23Gx1" Blue hub; C-Pre-filled Syringe D-Hub; E-Tip cap

Image amended to ensure accuracy with the proposed generic product & quality dossier



A-22Gx1½" Black hub; B-23Gx1" Blue hub; C-Pre-filled Syringe; D-Hub; E-Tip cap

Section 4. Clinical Particulars

4.4 Special Warnings And Precautions

Consider any quality differences in the generic product with respect to existing warnings in the reference PI.

- Are there warnings in the reference PI relating to excipients?
- Are all warnings appropriate to be retained in the generic PI?
- Are any new warnings clinically warranted?

Sulfite-sensitivity

[redacted] contains sodium metabisulfite, which may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is uncommon and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic subjects.

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Section 6. Pharmaceutical Particulars

6.1 List Of Excipients

- AANs **must** be used
  - e.g. glucose not ~~dextrose~~
- **Do not** use supplier trade names
  - e.g. polysorbate 80 not ~~Tween 80~~
- For colourants, **do not** include European food additive ‘E’ numbers
  - e.g. titanium dioxide ~~(E171)~~
- **Do not** include quantities of excipients
  - e.g. lactose ~~110 mg~~
- Proprietary ingredients in eBS – include the name and ID of proprietary ingredient
  - e.g. Include the full name of the proprietary ingredient followed by the proprietary ingredient ID.
    - i.e. **TekPrint SW-9009 Black Ink (ID 2343)**
- Proprietary ingredient not in the eBS – **must** list all sub-excipients

  Sub-excipients with known effect **must** also be listed in Section 2 of PI.

  Printing ink and **Fragrance** Proprietary ingredients **must** have an ID number i.e. when sub-ingredients not individually listed.

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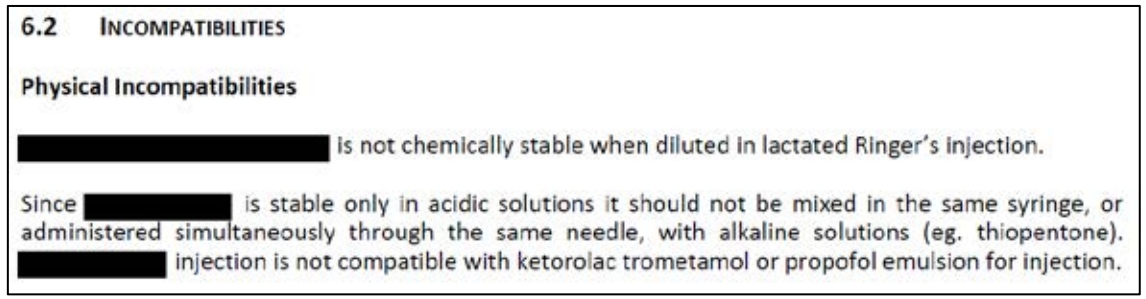
Section 6. Pharmaceutical Particulars

6.2 Incompatibilities

- List incompatibilities with dilution solvents, excipients, active substances, tubing, infusing bags, delivery systems etc.
- If relevant, a cross-reference to 'Section 4.5 – Interactions with other medicines and other forms of interactions' may be included.

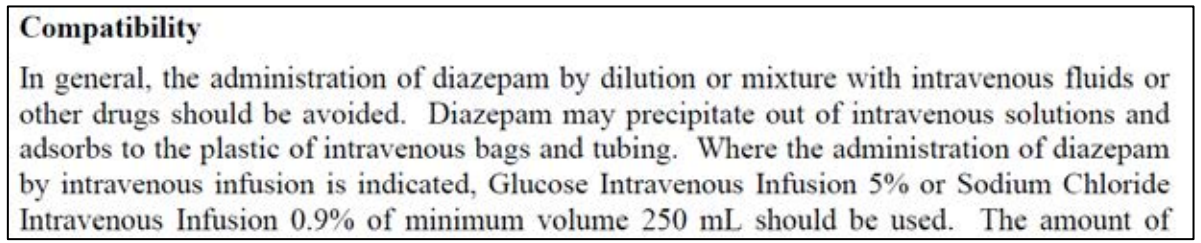


6.2 INCOMPATIBILITIES

Physical Incompatibilities

[redacted] is not chemically stable when diluted in lactated Ringer's injection.

Since [redacted] is stable only in acidic solutions it should not be mixed in the same syringe, or administered simultaneously through the same needle, with alkaline solutions (eg. thiopentone). [redacted] injection is not compatible with ketorolac trometamol or propofol emulsion for injection.



Compatibility

In general, the administration of diazepam by dilution or mixture with intravenous fluids or other drugs should be avoided. Diazepam may precipitate out of intravenous solutions and adsorbs to the plastic of intravenous bags and tubing. Where the administration of diazepam by intravenous infusion is indicated, Glucose Intravenous Infusion 5% or Sodium Chloride Intravenous Infusion 0.9% of minimum volume 250 mL should be used. The amount of

If registered prior to 1 January 2018 and the approved PI did not require a statement on incompatibilities, then following can be used:

'Incompatibilities were either not assessed or not identified as part of the registration of this medicine.'

Section 6. Pharmaceutical Particulars

6.3 Shelf Life

Use the standard statement in lieu of explicit shelf life. – **preferred**

> '**In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging**'.

INJECTION PRODUCTS requiring RECONSTITUTION/DILUTION

If reconstituted, diluted (or both) and then stored before use:

- There are many conflicting statements between chemical storage times and microbial storage times. From a microbial perspective:
  - **Up to 24 hours when stored under refrigerated conditions between 2 °C – 8 °C or**
  - **Up to 6 hours when stored at room temperature.**
- Any proposed in-use storage conditions **greater than** these must be supported by **both** chemical/physical and **microbiological** data.

Section 6. Pharmaceutical Particulars

6.4 Special Precautions For Storage

Store below XX °C – required. Refer to Section 11(5) of TGO 91.

Include additional storage conditions – i.e., ‘Protect from light’.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

This medicinal product does not require any special storage conditions.

Warnings on the labels and in the PI must be the same.

Section 6. Pharmaceutical Particulars

6.5 Nature And Contents of Container

- **Include all proposed pack sizes that are registered.**
  Optional text: *"**not all pack sizes may be marketed**".*
- **Include reference to the material of construction of the immediate container.**
  e.g. PVC/Al blister or HDPE bottle with child-resistant closure.
  e.g. clear Type I glass vial with rubber stopper and aluminium flip off cap with blue button.
- **Include other components of the kit.**
  e.g. Needles, syringes, inhalers, measuring spoons, etc.

[redacted] is provided in a pre-filled syringe (cyclo-olefin-copolymer) with backstop, a plunger stopper and tip cap (bromobutyl rubber). The kit contains 2 safety needles (a 1½-inch 22 gauge safety needle and a 1-inch 23 gauge safety needle).

6.5 NATURE AND CONTENTS OF CONTAINER

[redacted] 60 mg tablets are available in opaque, high-density polyethylene bottles with child-resistant polypropylene closure and induction seal liner. Each bottle contains 120 tablets and a desiccant.

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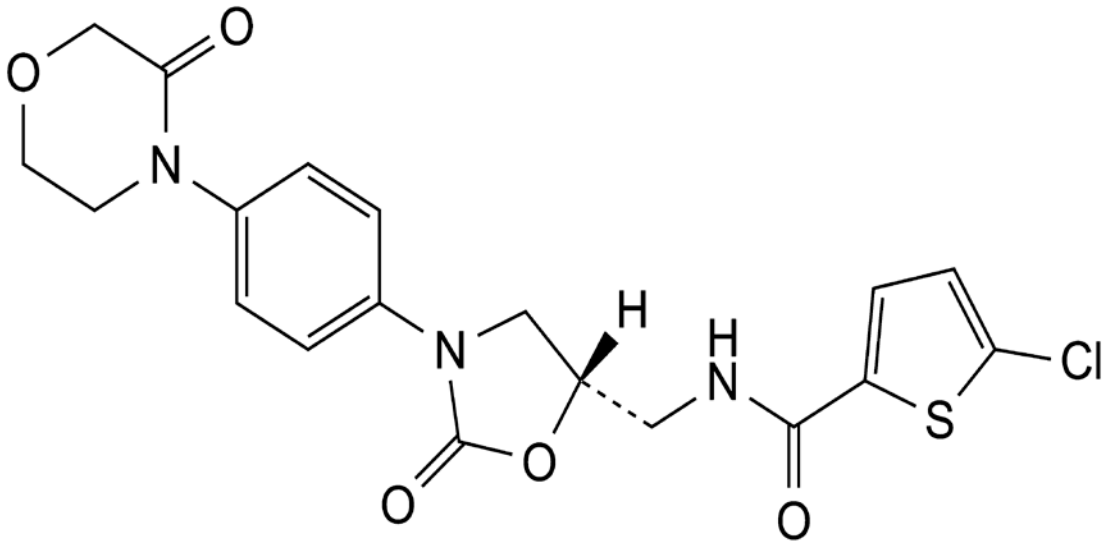
Section 6. Pharmaceutical Particulars

6.7 Physicochemical Properties

- **Chemical structure**

  Except for simple salts, complex molecules and biologicals (simple schematic preferred) or if the structure is not defined.

  Should match the active ingredient in Section 1.



- **Clinically relevant physicochemical properties**.

  e.g. Solubility, pH, osmolarity, molecular weight

  Previously located in Section 2. **Preferred** location is under Section 6.7.

- **CAS number & chemical formula.**

  Ensure formula is correctly formatted (i.e. subscript numbers) – ensure CAS is correct.

Section 7. Medicine Schedule (Poisons Standard)

Confirm that:

- Schedule is the same for all pack sizes.
- There has been no change to the schedule.

Preferred presentations:

S4 - Prescription Only Medicine.

Schedule 4 - Prescription Only Medicine.

Schedule 4 - Prescription only medicines and prescription animal remedies

DICLOFENAC **except**:

(a) when included in Schedule 2 or 3; or

(b) in preparations for dermal use unless:

(i) for the treatment of solar keratosis; or

(ii) containing more than 4% of diclofenac.

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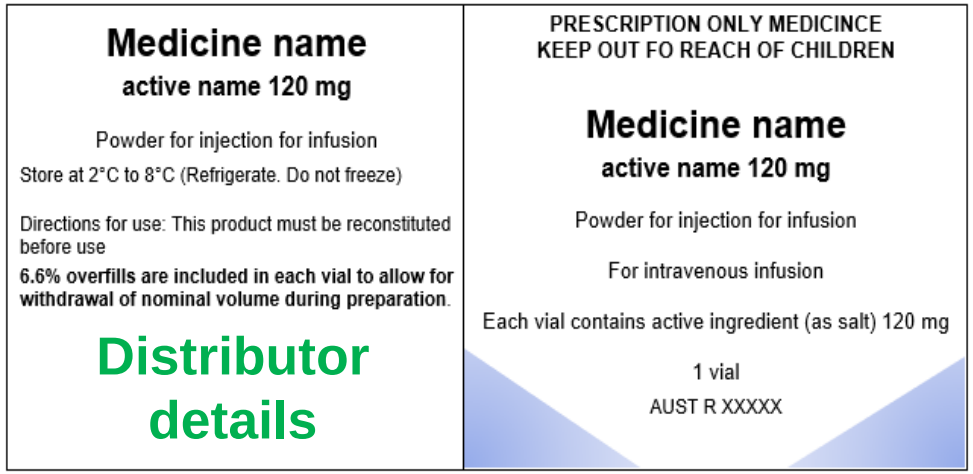
Section 8. Sponsor

It is a mandatory requirement that the sponsor, their address and contact details must be included in section 8.

TGO 91 allows for the name of the sponsor or distributor and sufficient information to allow the sponsor or distributor to be uniquely identified to facilitate public contact on matters of complaint, use or general enquiry, on the labels.



If the labels only state the distributor

Best practice

8 SPONSOR

Sponsor name
Sponsor address
Sponsor contact details

&

Distributor name
Distributor address

state both the sponsor and the distributor name and address, and contact details (phone, e-mail, website) for the sponsor

Top 10 issues

1. The PIs for individual trade names are not identical.
2. Differences from the reference PI are not supported by an appropriate justification.
3. Inconsistent formatting of text and tables from the reference PI.
4. PI Title is incorrect.
5. Single dose injection presentations stated as mg/mL.
6. Excipients with known effect declaration is missing or incorrect.
7. AANs not used.
8. Storage statements and warnings do not match the labels.
9. Container descriptions not included.
10. Contact details for sponsor/distributor not present.

What's next?

- Webinar slides will be made available
- Guidance document on Preparing a Product Information for a generic medicine – **coming soon**
- Visit the TGA booth at

ARCS AUSTRALIA

2024 ARCS Annual Conference

ICC Sydney, 12-14 June 2024

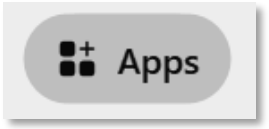
Contact us

PI Webinar QUERIES

pcsinbox@health.gov.au

How did we go?

Take a moment to complete our survey



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Website and link references

Approved Form for providing product information	https://www.tga.gov.au/resources/resource/guidance/form-providing-product-information
Reformatting Product Information: Frequently asked questions	https://www.tga.gov.au/resources/resource/guidance/reformatting-product-information-frequently-asked-questions
Mandatory requirements for an effective application	https://www.tga.gov.au/resources/resource/guidance/mandatory-requirements-effective-application
PCS Inbox	pcsinbox@health.gov.au
Product Information, Ingredients and Proprietary Ingredients search on eBS	https://www.ebs.tga.gov.au/
Stability testing for prescription medicines (Formerly ARGPM 14)	https://www.tga.gov.au/sites/default/files/stability-testing-prescription-medicines.pdf
Poisons Standard (Formerly SUSMP)	https://www.legislation.gov.au/F2024L00095/latest/text
Therapeutic Goods Order 91 - Standard for labels of prescription and related medicines	https://www.legislation.gov.au/F2016L01285/latest/versions
Updates to Australian medicine labelling rules to support medicine safety – Public consultation	https://consultations.tga.gov.au/medicines-regulation-division/updates-to-australian-medicines-labelling-rules/

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