



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of PARACETAMOL KABI paracetamol 1000mg/100mL solution for injection in freeflex bag (AUST R: 218687) and PARACETAMOL KABI paracetamol 1000mg/100mL solution for injection vial (AUST R: 203624) and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.

The above Australian registered medicines sponsored by Fresenius Kabi Australia Pty Ltd are currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until **31st October 2024** for the following indication(s):

Indicated for the relief of mild to moderate pain and the reduction of fever where an intravenous route of administration is considered clinically necessary.

PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel) is registered and marketed in Israel by Raz Pharmaceuticals, the label is in Hebrew and English languages.

Please note: Difference in labelling of strength
The section 19A medicine strength is specified as 10mg/mL on the label.
The Australian registered medicine strength is specified as 1000mg/100mL on the label.
The section 19A medicine is equivalent in concentration and volume to the Australian registered product.

A comparison table between the Australian registered **PARACETAMOL KABI paracetamol 1000mg/100mL solution for injection vial (AUST R: 203624)** and the section 19A product **PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel)** is given below:

| | PARACETAMOL KABI paracetamol 1000mg/100mL solution for injection vial (AUST R: 203624) | PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel) |
|---------------------|--|---|
| Presentation | Clear to slightly yellowish solution. Clear glass vials in packs of 12 vials | The solution is clear, colourless solution or slightly coloured from amber-yellow to pink-pale orange. Polypropylene bottles in packs of 30 bottles |
| Excipients | -Mannitol -Cysteine hydrochloride -Nitrogen (as protective gas) -Water for injections | - Glucose monohydrate - Sodium citrate dihydrate - Acetic acid - Sodium acetate trihydrate -Hydrochloric acid /Sodium hydroxide -Water for injections |
| Storage | Store below 25°C. Do not refrigerate or freeze. | Store below 25°C. |

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| | | Store in its original package, protect from light. Do not refrigerate or freeze. |
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Pro Pharmaceuticals Group recommends that healthcare professionals disregard the information leaflet contained within the pack and refer to the Australian approved Product Information for **PARACETAMOL KABI paracetamol 1000mg/100mL solution for injection vial (AUST R: 203624)** and **PARACETAMOL KABI paracetamol 1000mg/100mL solution for injection in freeflex bag (AUST R: 218687)** when prescribing and administering **PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel)** available at www.ebs.tga.gov.au/

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **PARACETAMOL S.A.L.F 10mg/mL (1000mg/100mL) solution for infusion bottle (Israel)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director Pro Pharmaceuticals Group