

9<sup>th</sup> September 2022



**RE: Shortage of AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle and alternative supply arrangement under Section 19A of the Therapeutic Goods Act.**

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Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720**, LINK has arranged the supply of an alternative product, **Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)** registered and marketed in the United States of America.

**Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)** 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 **28 February 2023**.

**Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)** is indicated for:

*Treatment of the following infections due to susceptible strains of sensitive organisms:*

*Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. Amoxicillin alone or in combination with another antibiotic, may be used in an emergency where the causative has not been identified.*

- *Respiratory tract infections (acute and chronic): H. influenzae; Streptococcus; S.pneumoniae; Staphylococcus, nonpenicillinase producing; E. coli.*
- *Urogenital infections (complicated and uncomplicated, acute and chronic): E.coli P.mirabilis and Strep. faecalis.*
- *Gonorrhoea: N. gonorrhoea (nonpencillinase producing).*
- *Skin and skin structure infections: Staphylococcus, nonpenicillinase producing; Streptococcus; E. coli.*
- *Prophylaxis of endocarditis: Amoxicillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with a prosthetic heart valve or those who have previously had endocarditis.*

**The s19A approved US product is identical in active ingredient and strength to the Australian registered product.** Please note the differences between the products as displayed in the table below.

|                   | <b>ARTG product<br/>AMOXYCILLIN SANDOZ amoxicillin<br/>trihydrate 250mg/5mL powder for oral<br/>suspension bottle ARTG: 93720</b>   | <b>Amoxicillin powder for oral suspension<br/>250mg/5mL (West-Ward)</b>   |
|-------------------|---|---|
| <b>Excipients</b> | <ul style="list-style-type: none"><li>• Anhydrous citric acid,</li><li>• sodium benzoate,</li><li>• aspartame,</li><li>• purified talc,</li><li>• sodium citrate anhydrous,</li><li>• guar gum</li><li>• silicon dioxide,</li><li>• lemon flavouring,</li><li>• peach-apricot flavouring,</li><li>• orange flavouring</li></ul> | <ul style="list-style-type: none"><li>• Colloidal silicon dioxide</li><li>• Hypromellose</li><li>• Sodium benzoate</li><li>• Sucrose</li><li>• Trisodium citrate dihydrate</li><li>• Tutti frutti flavor</li><li>• Xanthan gum.</li></ul> |

|                |  |  |
|----------------|--|--|
|                | <b>ARTG product</b><br><b>AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720</b>  | <b>Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)</b>  |
| <b>Storage</b> | <b>Powder:</b> Store below 25 °C. Keep the container tightly closed.<br><b>After Mixing:</b> Store in a refrigerator (2 °C-8 °C). Discard unused suspension after 14 days. | Store at 20° to 25°C<br>Any unused portion of the reconstituted suspension must be discarded after 14 days. Refrigeration is preferable, but not required. |

**Please note:** The 19A approved product contains sucrose, it is **NOT** sugar free.

Please refer to the Australian Product Information for **AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)**.

**Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)** is registered in **the United States of America** with the outer package and package insert both in *English*. The active ingredient, strength and dosage form included on the bottle label are in English.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Amoxicillin powder for oral suspension 250mg/5mL (West-Ward)** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at [medinfo@linkhealthcare.com.au](mailto:medinfo@linkhealthcare.com.au).

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at [customerservice@linkhealthcare.com.au](mailto:customerservice@linkhealthcare.com.au).

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720**.

Yours sincerely,



Charlotte Griffin

Medicine Access Associate