

1st April 2024

**RE: Medicine Shortage of ASACOL[®] (mesalazine) 800 mg (File ref: TT50-4507b)
enteric coated tablet blister pack, alternative Supply of English
Labelled Australian Pack Under Section 29**

Dear Doctor,

The New Zealand registered medicine - ASACOL[®] (mesalazine) 800 mg (File ref: TT50-4507b) enteric coated tablet blister pack sponsored by Chiesi New Zealand Limited t/a Emerge Health (Chiesi New Zealand), is out of stock due to international supply constraints.

Chiesi New Zealand has been able to arrange supply of the same product in overseas labelled packaging on a temporary basis. The product is NOT registered in New Zealand and supply is authorised under an approval granted by Medsafe under Section 29 for the following indication:

ASACOL[®] (mesalazine) 800 mg enteric coated tablets are indicated for:

- Ulcerative Colitis: Induction of remission of mild to moderate episodes, and maintenance of remission.¹
- Crohn's ileo-colitis: Maintenance of remission.¹

ASACOL[®] (mesalazine) 800 mg has been registered and marketed in Australia since the 21st of September 2016.²

The Consumer Medicine Information package leaflet of ASACOL[®] (mesalazine) 800 mg differs between the Australian registered product and New Zealand product.

- The Australian Consumer Medicine Information package leaflet contains information about a 1600 mg mesalazine strength tablet, which is currently not registered in New Zealand.
- The Australian Consumer Medicine Information package leaflet does not contain any information about ASACOL[®] (mesalazine) 16.67% w/w 500 mg suppositories, which are currently not registered in Australia.

ASACOL NZ-ASA-2400003 Date of Preparation March 2024
ASACOL[®] is a registered trademark of Tillotts Pharma AG. Distributed in New Zealand by Chiesi New Zealand Limited t/a Emerge Health.

1. ASACOL[®] Approved Data Sheet.
2. ASAACOL[®] Approved Product Information



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Patients/care givers should be advised to disregard the package leaflet contained within the overseas pack and refer to the New Zealand Consumer Medicine Information available from the pharmacist or at www.medsafe.govt.nz/Medicines/infoSearch.asp.

Pharmac Reimbursement

ASACOL[®] (mesalazine) 800 mg enteric coated tablets are available on the Pharmac Pharmaceutical Schedule. Please refer to the Pharmaceutical Schedule for full authority information.

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 the Australian ASACOL[®] (mesalazine) 800 mg product should be reported by healthcare professionals and patients to Chiesi New Zealand on 09 951 3003 or by email to: pv.au@chiesi.com. Alternatively, Healthcare professionals can report any suspected adverse reactions <https://pophealth.my.site.com/carmreportnz/s/>.

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

For further information, please contact Chiesi New Zealand on the details listed below.

Yours sincerely,

Carl Arico

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