July 2018

Dear Healthcare Professional,

Sanofi would like to inform you of a temporary supply shortage of New Zealand approved NEULACTIL periciazine 2.5mg (TT50-0613) and 10mg tablets (TT50-0613a). Medsafe is aware of the temporary supply shortage.

Sanofi is in the process of changing the manufacturing site of Neulactil, and there have been unforeseen delays in in the transfer. Sanofi is making every effort to resolve the issue and anticipate to be back in stock within 12 months. Please inform your patients of the current situation.

Sanofi is currently able to supply Neulactil 2.5mg and 10mg tablets sourced from Hong Kong. These products have been granted provisional consent under section 23 of the Medicines Act 1981 for a period of 12 months. Provisional consent has been granted due to the high clinical need to ensure continuity of supply for the following indications:

1. In adults with schizophrenia or other psychoses, for the treatment of symptoms or prevention of relapse.
2. In anxiety, psychomotor agitation, violent or dangerously impulsive behaviour. Periciazine is used as an adjunct to the short-term management of these conditions.

The New Zealand and Hong Kong versions of Neulactil are the same with regards to the active ingredient, strength and indications; however the two products differ slightly in their formulations, presentation, pack size and packaging. Please refer to the Medsafe website to access the data sheet[1].

Formulation:

- The New Zealand registered Neulactil includes the following excipients: microcrystalline cellulose; lactose monohydrate; magnesium stearate; colloidal anhydrous silica and wheat starch
- The Hong Kong Product includes: Cellulose, microcrystalline (E460); Anhydrous lactose, Magnesium stearate; Silica colloidal anhydrous (E551); Sodium starch glycolate; **Methyl parahydroxybenzoate (E218)**

Presentation:

- The New Zealand registered Neulactil:
    - 2.5 mg tablets: Circular, yellow tablet, with one face impressed Neulactil just inside the perimeter. Break-line on reverse. 100 tablets
    - 10 mg tablets: Circular yellow tablet, one side scored. Marked 10 on the reverse. 100 tablets
- The Hong Kong product:
    - 2.5mg tablets: Circular, very pale lime-yellow tablet, with one face impressed Neulactil just inside the perimeter. Break-line on reverse. 84 tablets.
    - 10mg tablets: Circular, very pale lime-yellow tablet, with one face impressed Neulactil just inside the perimeter around a central 10. Break-line on reverse. 84 tablets.

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Packaging:

The Neulactil manufactured for the Hong Kong market has Hong Kong specific labelling, which is similar to the New Zealand labelling, and has been reviewed and approved by Medsafe.

- New Zealand packaging has the spelling 'Periciazine' and the Hong Kong packaging has the spelling 'Pericyazine' – these are synonyms for the same active ingredient.

PHARMAC Reimbursement

Hong Kong approved Neulactil will be reimbursed under the Pharmaceutical Schedule in the same way as New Zealand approved Neulactil. Prescriptions should be written in the normal manner.

Adverse Event Reporting

Reporting any suspected adverse events is important for the continued monitoring of the safety of all medicines. You are encouraged to report any suspected adverse events via the Centre for Adverse Reaction Monitoring or directly to Sanofi at ae@sanofi.com.

If you would like further information regarding Neulactil please contact:

Medical enquiries	Sanofi Medical Information	0800 283 684 option 2
Enquiries relating to supply	Sanofi Customer Service	0800 726 634

I apologise for the inconvenience this variation in supply of Neulactil may cause and appreciate your understanding and support during this period. As further information becomes available, we will be in contact with you to provide an update.

Kind regards,

Krista Applebee
Medical Manager, General Medicines

1. *Neulactil DataSheet July 2018*


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