Canterbury District Health Board
Te Poari Hauora ō Waitaha

Clinical Pharmacology Bulletin

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26th February 2020

Levomepromazine 25 mg and 100 mg tablets – important note regarding product change

Key points:

- The current NZ Sanofi levomepromazine (Nozinan®) 25 mg and 100 mg tablets will be replaced with Swiss Sanofi Nozinan® formulations temporarily from 1st March 2020. They are *not* bioequivalent.
- Dose equivalency is **1 x NZ tablet ≈ 0.75 x Swiss tablet.**
- **All prescriptions should be annotated with "Swiss product".**
- Transition requires a review of the prescription for individual patients, and monitoring for altered clinical effect or toxicity. The most likely adverse drug effect is psychomotor impairment, such as sedation.
- For more information see www.medsafe.govt.nz, including patient information.

Sanofi are temporarily ceasing manufacturing of the NZ-approved levomepromazine (Nozinan®) 25 mg and 100 mg tablets due to manufacturing issues. To maintain supply, they will distribute 25 mg and 100 mg Nozinan® tablets from their factory in Switzerland from 1st March 2020. *These products are not bioequivalent.* The Swiss tablets will be distributed via Provisional Consent and should be funded from 1st March 2020. This change does not affect injection products.

What is levomepromazine used for?

Levomepromazine is an antipsychotic with marked sedative effects. The tablets may be used to reduce psychomotor activity in psychiatric patients. It is also used in palliative care for agitation or confusion (licensed indication), hiccups or nausea/vomiting.

How do the NZ and Swiss products differ?

- Swiss tablets contain more active drug. The NZ 25 mg and 100 mg tablets contain 25 mg or 100 mg of levomepromazine *maleate*. The Swiss 25 mg and 100 mg tablets contain 25 mg or 100 mg of levomepromazine *base*, which is equivalent to 33.75 mg or 135 mg of levomepromazine maleate.

1 x NZ tablet ≈ 0.75 x Swiss tablet

(1.5 x Swiss tablets ≈ 2 x NZ tablets)

Levomepromazine dose conversion table for prescribers:

Current dose (NZ tablets)	Equivalent to (Swiss tablets)	Potential doses with Swiss tablets (rounded) Annotate prescription with "Swiss tablets"	
			No. of 25 mg Swiss tablets
6.25 mg	4.69 mg	6.25 mg	¼
12.5 mg	9.38 mg	6.25 mg or 12.5 mg	¼ or ½
25 mg	18.75 mg	12.5 or 25 mg	½ or 1
50 mg	37.5 mg	37.5 mg	1½
75 mg	56.25 mg	50 mg	2
100 mg	75 mg	75 mg	3

* Most frequently prescribed doses are shown here using 25 mg tablets. However, 100 mg tablets are also available.

- Different appearance – the Swiss packaging has "levomepromazinum" on it and will be overlabelled in English. Swiss tablets are beige coloured; whereas NZ tablets are white. Both Swiss and NZ tablets are scored and can be halved or quartered if clinically necessary (although no data to support this).
- Different excipients - including lactose in the Swiss tablets. However, we do not expect lactose as an excipient to pose a problem for most patients who have lactose-intolerance.

What monitoring is necessary?

Patients should be monitored for reduced clinical efficacy if the dose is rounded down, or adverse effects if the dose is rounded up. Levomepromazine adverse effects include psychomotor impairment, particularly sedation; extrapyramidal symptoms, cardiovascular effects (e.g. QTc prolongation, postural hypotension), and anticholinergic effects. Patient information is available from www.nzf.org.nz. Report any suspected adverse reactions to CARM - https://nzphvc.otago.ac.nz/reporting/.

The information contained within this bulletin is provided on the understanding that although it may be used to assist in your final clinical decision, the Clinical Pharmacology Department at Christchurch Hospital does not accept any responsibility for such decisions.