12 February 2020

Dear Healthcare Professional,

IMPORTANT: CHANGE IN NOZINAN 25 mg & 100 mg TABLETS

Sanofi would like to inform you of a supply shortage of New Zealand approved Nozinan (levomepromazine maleate) 25 mg and 100 mg tablets. As an effort to avoid medicine discontinuation, Sanofi is supplying Nozinan tablets sourced from Switzerland. Medsafe has granted the Swiss Nozinan provisional consent under section 23 of the Medicines Act 1981 due to the high clinical need to ensure continuity of supply for the following indications:

Psychiatry - As an alternative to Largactil in schizophrenia, especially when it is desirable to reduce psychomotor activity.
General Medicine - Alone or together with appropriately modified doses of analgesics and narcotics, in the relief of severe pain and accompanying anxiety and distress.

The New Zealand and Swiss versions of Nozinan are the same with regards to the active ingredient however the two products differ in their active ingredient strength, formulations, presentation and packaging. Please refer to the Medsafe website to access the Data Sheet[1].

❖ **Differences in active ingredient strength:**
There is a difference in the levomepromazine maleate quantity between the New Zealand and Swiss formulation. Swiss tablets contain a greater amount of active than that of the New Zealand formulation:

1.5 x Swiss Nozinan tablets ≈ 2 x NZ Nozinan tablets

The table below provides a comparative guide to the number of tablets required to achieve the starting doses recommended in the NZ Data Sheet.

No. of tablets	**NZ Nozinan 25mg** Levomepromazine maleate content	**Swiss Nozinan 25mg** Levomepromazine maleate content	**NZ Nozinan 100mg** Levomepromazine maleate content	**Swiss Nozinan 100mg** Levomepromazine maleate content
0.5	12.5 mg	16.9 mg	50 mg	67.5 mg
1	25 mg	33.8 mg	100 mg	135 mg
1.5	37.5 mg	50.7 mg	150mg	202.5 mg
2	50 mg	67.6 mg	200 mg	270 mg

The Data Sheet Section 4.2 Dose and Method of Administration has been updated to add a statement:
'The recommended doses below refer to the amount of levomepromazine maleate contained in Nozinan tablets.'

IMPORTANT:
- **Bioequivalence has not been established between the NZ and Swiss products**
- **Doses will have to be adjusted when changing to the Swiss product**
- **Patients will need to be closely monitored to check if further dosage adjustment is necessary**

❖ **Differences in Formulation**

The differences in the excipients of the two products are tabulated below. Note that Swiss Nozinan contains lactose.

NZ Nozinan	potato starch	calcium carbonate	sodium lauryl sulphate	pulverised stearic acid	poly vinyl acetate	
Swiss Nozinan	**wheat starch**	hydrated colloidal silica	dextrin	yellow iron oxide E172	titanium oxide	**lactose monohydrate**

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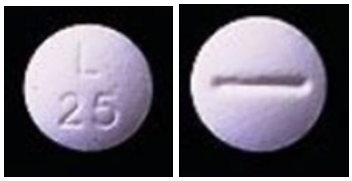
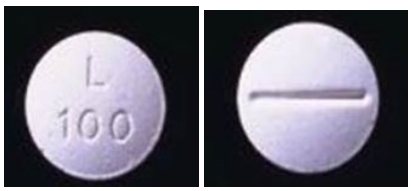
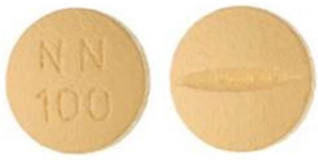
❖ **Differences in Presentation:**

Nozinan 25mg tablet	
New Zealand	**Swiss**
White, biconvex film-coated tablets indented 'L25' on one face with a break-line on the reverse. The diameter of the 25 mg tablets is 8.7 mm. 	Beige biconvex film-coated tablet indented 'NN 25' on one face with a break-line on the reverse. The diameter of the 25 mg tablets is 9mm. 
Nozinan 100mg tablet	
New Zealand	**Swiss**
White, biconvex film-coated tablets indented 'L100' on one face with a break-line on the reverse. The diameter of the 100 mg tablets 11.0 mm. 	Beige biconvex film-coated tablet indented "NN 100' on one face with a break-line on the reverse. The diameter of the 100mg tablets is 12mm. 

❖ **Differences in Packaging:**

The Swiss Nozinan is in Swiss pack, with the 'levomepromazine' spelled as 'levomepromazinum'. The pack is re-labelled in English to provide New Zealand-specific information. A patient letter will be provided with each Swiss pack. Additional copies of this letter can be found at https://www.medsafe.govt.nz/safety/DHCPLetters.asp.

PHARMAC Reimbursement

There is no change to the prescription charge as the Swiss product will be reimbursed under the Pharmaceutical Schedule in the same way as NZ Nozinan.

Adverse Event Reporting

Reporting any suspected adverse events is important for the continued monitoring of the safety of all medicines. You are asked to report any suspected adverse reactions to https://nzphvc.otago.ac.nz/reporting/ or email to carmnz@otago.ac.nz. You are also encouraged to report any suspected adverse events directly to Sanofi at ae@sanofi.com.

If you would like further information regarding Nozinan please contact:

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

We apologise for the inconvenience this variation in supply of Nozinan may cause and appreciate your understanding and support during this period. Sanofi is currently planning to keep supplying the Swiss Nozinan under the granted exemption till its expiry in February 2022. Please retain this letter for reference.

Kind regards,

James Scott
Medical Operations and Portfolio Manager – Primary Care

1. Nozinan Data Sheet, February 2020

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