6th December 2021

Cuprior® (trientine (as trientine tetrahydrochloride)) 150mg Film-coated tablet labelling exemption

Dear Healthcare Professional,

Te Arai BioFarma Limited would like to inform you of the following:

Summary

- A labelling exemption has been granted for supply of Cuprior® in New Zealand.
- The supplied labelling does not include the New Zealand approved storage condition "Stored at or below 25°C".
- Patients are to be made aware Cuprior® is to be stored at or below 25°C.

Background

Cuprior® is a medicine used to treat patients aged 5 years and older with Wilson's disease, a genetic condition in which copper absorbed from food builds up in the body, particularly in the liver and the brain, causing damage. Cuprior® is used in patients who cannot take D-penicillamine, another medicine for this condition.

Cuprior® contains the active substance trientine as trientine tetrahydrochloride. The trientine (as trientine tetrahydrochloride) in Cuprior® means it does not need to be stored in a refrigerator, unlike other trientine products which may be on the market. The New Zealand approved storage condition for Cuprior® is "Stored at or below 25°C".

A labelling exemption was granted allowing the use of EU labelling to be supplied in New Zealand. The EU carton does not include details about the storage condition. The package insert states "This medicine does not require any special storage conditions" versus the New Zealand storage condition "Stored at or below 25°C".

The patient is to be made aware Cuprior® is to be stored at or below 25°C.

The New Zealand approved storage condition of "Stored at or below 25°C" can be found on the New Zealand data sheet, consumer medicine information and the therapeutic products database, all found at www.medsafe.govt.nz.

Further information

If you have any questions or require additional information regarding the use of Cuprior® please email regulatory@tearaibiofarma.com.

Reporting adverse events

Email: regulatory@tearaibiofarma.com
Telephone: +64-9-889-5822 or 0800-TEARAI (0800-832724)
Postal: PO Box 46-205, Herne Bay, New Zealand 1147

Please report any suspected adverse events via email to adverse.event@tearaibiofarma.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by telephone on (03) 479 7247, by fax on (03) 479 7150, online at https://nzphvc.otago.ac.nz/reporting or by email to nzphvc@otago.ac.nz.

Yours sincerely,

Julia Reese

Director of Regulatory Affairs

Te Arai BioFarma Limited

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