




8th November 2016

Product Regulation
Medsafe
PO Box 5013
Wellington 6145

Dear Sir/Madam,

Re: Change to warning statements on labels of OTC loratadine or desloratadine medicines

 refers to the Medsafe consultation seeking feedback on the proposed changes to the labelling of over the counter medicines containing loratadine or desloratadine.

Currently loratadine as well as other second generation antihistamines require the following warning statement according to the Medsafe Label Statements Database (LSD):

- *Although this medicine is unlikely to affect your ability to drive or operate machinery, a few people may be impaired and care should be taken.*

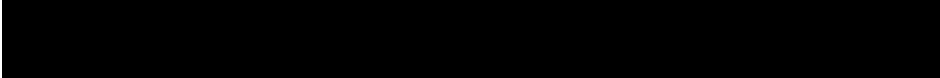
The proposal is to change the warning to differentiate between patients reporting drowsiness and patients reporting impaired driving. It was considered that the risk of sedation, although low, is higher than the risk of a patient experiencing impaired driving. Therefore the warning statement is proposed to be:

- *Very rarely, people get drowsy on this medicine. You should make sure you are not affected before doing activities that require full attention.*

We are concerned that the terminology “very rare” is not appropriate when considering the frequency of reported Adverse Events (AE’s) relating to sedation with 10mg Loratadine.

“Very rare” according to the internationally recognised CIOMs form, refers to an incidence of less than 1 in 10,000, when in fact the incidence of sedation while using 10mg loratadine is 1.2% above placebo¹ which makes it a “common” AE.

[CIOMs Frequency: Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1000, <1/100); rare (>1/10000, <1/1000); very rare (<1/10000 and including isolated reports)].



It's important to note that healthcare professionals are accustomed to the CIOMs terminology and format when considering the frequency of AE's, therefore to call out a warning as "very rare" on the LSD has the serious potential to cause confusion amongst healthcare professionals and their patients resulting in unsafe use of the product.

Based on the above we believe it would be more appropriate if the warning statement was amended to read something to the effect of:

- *Some people might get drowsy on this medicine. You should make sure you are not affected before doing activities that require full attention, such as driving or operating machinery.*

We also believe that this warning should be consistent across all OTC second generation anti-histamines. Globally, loratadine and cetirizine merit the same warning statements in relation to sedation with the exception of the US and Australia. It's important for Medsafe to consider the global landscape when making decisions affecting the label warnings on OTC medicines.

Table 1. Sedation warning requirements for second generation antihistamines globally

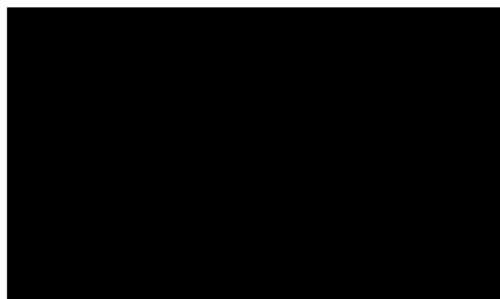
Country	Date of down scheduling to exempt (General sale)	Adult Dose Recommendation	Label Warning/Claims relating to sedation for Cetirizine and other OTC second generation anti-histamines
Canada	1995	10 mg per day	<ul style="list-style-type: none"> - Non-Drowsy claim on label - Some people can experience drowsiness due to allergies or antihistamine use. If drowsiness does occur with use, do not drive a car or operate machinery. <i>(Applicable to all second generation antihistamines)</i>
UK	2002	10 mg per day	<p>At the recommended dose, does not cause drowsiness in the majority of people. However, as with other antihistamines, rare cases of drowsiness have been reported. If affect do not drive or operate machinery. As with all antihistamine, you should avoid excessive alcohol consumption when taking this medicine.</p> <i>(Applicable to cetirizine and loratadine)</i>



USA	2007	10 mg per day	<p>When using this product</p> <ul style="list-style-type: none"> • Drowsiness may occur • Avoid alcoholic drinks • Alcohol, sedatives, and tranquilizers may increase drowsiness • Be careful when driving a motor vehicle or operating machinery <p><i>(Applicable to cetirizine only)</i></p>
New Zealand	2012	10 mg per day	<ul style="list-style-type: none"> - Non-Drowsy claim on label - Although this medicine is unlikely to affect your ability to drive or operate machinery, a few people may be impaired and care should be taken. <p><i>(Applicable to all second generation antihistamines)</i></p>

If you require any further information please don't hesitate to contact me.

Yours faithfully,



1. <https://www.medicines.org.uk/emc/medicine/29552>

