



# Principles for terminology used in permitted indications

*This fact sheet outlines the general principles applied to achieve consistency in the terminology used for permitted indications.*

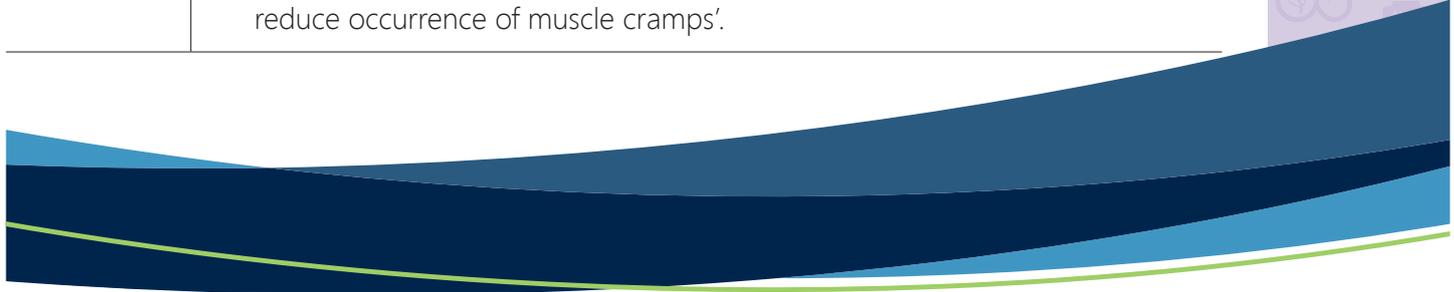


## Use of specific target qualifiers

References to <b>'mild'</b> forms of conditions	The target qualifier 'mild' is used to exclude serious forms of disease, ensuring that the indication only makes reference to a non-serious form of a disease, condition, ailment or defect, for example: 'mild arthritis'. The qualifier 'mild' cannot be used for conditions that require ongoing medical management, such as rheumatoid arthritis, asthma. Where a permitted indication includes the term 'mild' this <b>must</b> also be included on the medicine's label.
Reference to <b>'medically diagnosed'</b> conditions	For a <b>limited</b> number of conditions, it may be appropriate for a person to self-manage and assess the symptoms of their condition after an initial diagnosis has been made by a medical practitioner (where other diseases and conditions have been ruled out), for example: irritable bowel syndrome.  In these circumstances, the indication target (that is, the disease, condition, ailment or defect) may be qualified with 'medically diagnosed'. A required label statement will be 'If symptoms persist or worsen, consult your doctor'. Where a permitted indication includes the term 'medically diagnosed' this <b>must</b> also be included on the medicine's label.

## Use of action qualifiers

<b>'helps'</b>	The action qualifier 'helps' is included in a core permitted indication where: <ul style="list-style-type: none"><li>• A consumer is not able to self-assess the efficacy of the medicine, for example: 'Helps protect body cells from free radical oxidative damage'.</li><li>• The product is not having a direct effect but rather helping the body achieve a physiological effect. For example, taking a calcium supplement does not directly build the bone but it provides the resources for your body to build bone, therefore the indication appropriate to use is 'Helps strengthen bones'.</li><li>• The indication would otherwise be considered to infer a definitive treatment or a cure and be considered a higher level indication, for example: 'Helps reduce occurrence of muscle cramps'.</li></ul>
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## Use of action qualifiers

<b>'may'</b>	The word 'may' has not been used in permitted indications as it can imply that the sponsor does not have evidence of sufficient quality to show that their medicine is effective. This is not consistent with the legislative requirement for sponsors to hold evidence for the indications they make for their medicine.
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## Use of specific action terms

<b>'reduce / decrease / relieve'</b>	Where it is possible for a consumer to self-assess whether the medicine is reducing/decreasing/relieving their symptoms, these do not need to be qualified with 'helps', for example: 'Decrease/reduce/relieve itchy skin'.
<b>'increase'</b>	<p>'Increase' is not used where it would infer/imply the correction of an abnormal state, for example: 'Increase thyroid function' and 'Increase fertility'.</p> <p>However, where the indications does not imply correction of an abnormal state and, where a consumer can self-assess the efficacy of the medicine, 'increase' may be appropriate to use, for example; 'Increase body relaxation'.</p>
<b>'maintain / support'</b>	The terms 'maintain/support' are considered to be lower level health claims that refer to general health maintenance. As such, these are not usually qualified with the term 'helps'.
<b>'enhance / promote'</b>	Where it is possible for a consumer to self-assess health enhancement claims these are not qualified with 'helps'. For example, 'Enhance promote skin health' is able to be assessed by the consumer, while 'Enhance/promote heart health' is not, and so is qualified with 'Helps enhance/promote heart health'.
<b>'prevention' vs 'reduce frequency of symptoms'</b>	In certain circumstances 'Helps reduce the frequency of symptoms....' is used where it is not considered to infer treatment or prevention of the condition itself. Rather, it is a risk reduction for the occurrence or of symptoms, for example: 'Reduce the frequency of symptoms of menopause'.



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