

**Policy document**  
**Statement of ‘abbreviated indications’ on**  
**packaging of OTC medicinal products**

**MEB 21**  
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## 2. Abbreviations and definitions

MEB	Medicines Evaluation Board
SmPC	Summary of Product Characteristics
OTC	Over-the-counter medicinal products

## 3. Introduction

Directive 2001/83/EC discusses European regulations on labelling. In accordance with Article 54(n), the outer packaging of over-the-counter (OTC) medicinal products (i.e. non-prescription medicinal products) must contain 'instructions for use'. This also includes the complete indication area, in line with the Summary of Product Characteristics (SmPC). This statement must be described in patient-friendly language, in accordance with the package leaflet.

To clarify the data referred to in Article 54, symbols or pictograms may be placed on the outer packaging and in the package leaflet. Other information that is in line with the SmPC and that contributes to health education can also be added. Information that could have a promotional effect may not be placed. This is in accordance with Article 4a.1, first paragraph of the Medicines Act Regulations and Article 62 of Directive 2001/83/EC.

Thus, the packaging may not contain any information, claims or logos, symbols or pictograms that:

- conflict with the SmPC, as approved by the Medicines Evaluation Board (MEB),
- provide information to promote use of the product,
- do not contribute to the information about the medicinal product and/or its proper use.

The MEB has laid down the above-mentioned information in policy document MEB 6: Labelling of pharmaceutical products.

## 4. Frame

To clarify the information on the indication area of OTC medicinal products for the patient, the MEB has decided that, in addition to the mandatory information, the indication may be displayed in abbreviated form on the main side of the outer packaging. In specific cases, the manufacturer may add additional information about the indication area in the form of specifically recognisable substance characteristics instead of an abbreviated indication.

## 5. Procedure

The abbreviated indication or abbreviated information on the indication area is documented on the basis of the following criteria:

- The use of this additional information is optional.
- This additional information must be assessed and approved by the MEB.
- This additional information is only permitted for OTC medicinal products.
- The additional information may not create confusion with respect to the (complete) description of the indication area, in accordance with the SmPC.
- The additional information may not suggest a broader indication area than the indication area documented in the SmPC, e.g. by leaving out limiting sentences or phrases. It is also not acceptable to mention fewer indications than stated in the SmPC because this can cause confusion about the use of the product and can result in overuse.
- The abbreviated indication should preferably be based on symptoms that are (easily) recognisable and/or determinable for the patient.
- The 'complete' description of therapeutic indications, in line with the SmPC and in patient-friendly terms, must remain on the packaging.
- The additional information may not be seen/interpreted as a replacement of the mandatory information. To avoid confusion, the additional information must always be secondary to the name of the medicinal product and, as such, may never be displayed more prominently on the packaging.
- The packaging text must meet all other statutory regulations.

### Traditional herbal medicinal products

In addition to the above-mentioned criteria, the MEB also permits the statement of abbreviated information about the indication area for traditional herbal medicinal products, provided it states directly below the abbreviated statement on the indication area: 'Traditional herbal medicinal product'. The abbreviated information about the indication area and the statement of 'Traditional herbal medicinal product' form a single entity and should also be expressed as such on the packaging. The abbreviated indication of traditional herbal medicinal products must also be based on symptoms that are (easily) recognisable and determinable for the patient.

### Determination of abbreviated indication

After approval by the MEB, the abbreviated information about the indication area will be included in the lists on the following pages. These lists were created for more consistency in the way the user is informed about a certain product. A marketing authorisation holder can submit a request to the MEB for an abbreviated description of the indication area to be determined for an active ingredient or a herbal ingredient that has not yet been listed. This request can be made during an ongoing application or by submitting a variation procedure.

## 6. List of abbreviated information on the indication area for active ingredients

### Analgesics

Bij koorts en bij pijn

Substances listed below, possibly in combination, whether or not supplemented with caffeine and/or ascorbic acid

Koorts en pijn bij griep en verkoudheid\*

- acetylsalicylic acid\*\*
- carbasalate calcium
- ibuprofen\*\*
- naproxen\*\*
- paracetamol
- propyphenazone
- diclofenac potassium\*\*

\* The MEB prefers the use of “Bij koorts en bij pijn”

\*\* Specifically for these NSAIDs, the following additional information on the indication area may be chosen instead of the abbreviated indication:

- anti-inflammatory,
- fever-reducing,
- analgesic.

### Muscle pain medicinal products

Bij spierpijn

- diethylamine salicylate

The combination:

- capsicum extract,  
glycol salicylate, histamine  
dihydrochloride  
and methyl nicotinate

### Ear ache medicinal products

Bij oorpijn

- lidocaine hydrochloride

### Cough medicinal products

Bij vastzittende hoest door taai slijm

- bromhexine hydrochloride

Substances listed below, possibly in combination:

- acetylcysteine
- carbocysteine

Bij prikkelhoest

- noscapine
- dextromethorphan
- pentoxyverine

## Nasal catarrh

Bij neusverkoudheid

Substances listed below, possibly in combination:

- tramazoline hydrochloride
- oxymetazoline
- xylometazoline hydrochloride
- camphora,
- menthol
- eucalyptol,
- chloorthymol

## Sore throat medicinal products

Bij beginnende keelpijn

- dequalinium chloride
- cetylpyridinium chloride
- phenol
- menthol

Bij keelpijn

- ambroxol hydrochloride
- flurbiprofen
- lidocaine hydrochloride

The combination:

- lidocaine hydrochloride, amylmetacresol and dichlorobenzyl alcohol

The combination:

- lidocaine hydrochloride and propyl parahydroxy benzoaat

## Allergy medicinal products

Bij hooikoorts en vergelijkbare allergische reacties

- azelastine
- cetirizine dihydrochloride
- loratadine
- sodium cromoglicate (nasal spray or eye drops 20 mg/ml only)

The term "neusallergie" is preferred instead of "hooikoorts".  
"Galbulten/netelroos" may be added.

## Contraception / Emergency contraception

Nood-anticonceptie • levonorgestrel\*

\* With the indication: Emergency contraception within 72 hours after unprotected sexual intercourse or failure of a contraceptive method.

## Anti-lice medicinal products

Ter bestrijding van luizen \* • malathion

Ter bestrijding van hoofdluis\* • permethrine

\* can be supplemented with 'en neten' provided it is in accordance with the SmPC.

## Wound disinfection

Desinfectie bij snij- schaaf- en brandwonden • povidone iodine

Voor huid- en wondontsmetting • chlorhexidine

Voor wondontsmetting • benzalkonium chloride

## Dermatological medicinal products

Bij schimmelinfecties van de huid • clotrimazole  
• miconazol nitrate\*  
• sulconazole  
• terbinafine\*

\* "(o.a. voetschimmel)" may be added to the abbreviated indication.

Bij haaruitval van mannen • minoxidil

Bij jeugdpuistjes • benzoyl peroxide

The combination:

- miconazolnitrate and benzoyl peroxide

Bij huidirritaties • zinc oxide

Bij luierslag • zinc oxide

Bij koortslip • aciclovir  
• penciclovir

Tegen wratten • salicylic acid

## Laxatives

- |                           |   |
|---------------------------|---|
| Bij moeilijke stoelgang   | <ul style="list-style-type: none"> <li>• bisacodyl</li> <li>• sodium picosulfate</li> <li>• sorbitol</li> <li>• sodium lauryl sulfate</li> <li>• macrogol+elektrolytes</li> </ul> |
| Tegen moeilijke stoelgang | <ul style="list-style-type: none"> <li>• lacticol</li> <li>• lactulose</li> </ul>   |

## Anti-diarrhoeal medicinal products

- |  |   |
|--|---|
| Bij diarree  | <ul style="list-style-type: none"> <li>• Loperamide hydrochloride</li> </ul>              |
| Bij diarree gepaard gaand met krampen, opgeblazen gevoel of winderigheid | <ul style="list-style-type: none"> <li>• Loperamide hydrochloride + simeticone</li> </ul> |

## Stomach and gastrointestinal medicinal products

- |  |   |
|--|---|
| Bij brandend maagzuur en zure oprispingen                                  | <ul style="list-style-type: none"> <li>• famotidine</li> <li>• ranitidine</li> <li>• omeprazole</li> </ul>  |
| Bij brandend maagzuur en zure oprispingen, (of) Verlicht brandend maagzuur | <ul style="list-style-type: none"> <li>• pantoprazole</li> </ul>  |
| Bij brandend maagzuur en zure oprispingen                                  | <p>Substances (or base of substances) listed below, possibly in combination</p> <ul style="list-style-type: none"> <li>• algeldrate</li> <li>• hydrotalcite</li> <li>• magnesium carbonate</li> <li>• magnesium hydroxide</li> <li>• calcium carbonate</li> </ul> |

And the two substances listed below only in combination with one or more of the above-mentioned base of substances

- |  |   |
|--|---|
|  | <ul style="list-style-type: none"> <li>• alginic acid</li> <li>• alginate</li> </ul>  |
| Bij buikkrampen  | <ul style="list-style-type: none"> <li>• butylscopolamine bromide</li> </ul>  |
| Bij een opgeblazen gevoel, bij brandend maagzuur of zure oprispingen | <p>De combinatie:</p> <ul style="list-style-type: none"> <li>• simeticone, calcium carbonate and magnesium carbonate</li> </ul> |



### Nicotine products

- Bij stoppen met roken
- nicotine

### Other

- Voorkomt tandbederf
- sodium fluoride
- Ter bestrijding van wormpjes
- mebendazole
- Wanneer elastische kousen onvoldoende helpen
- hydroxyethylrutosides
- Bij nervositeit en spanning
- valerian extract
- Bij reisziekte
- cinnarizine\*

\* For this specific medicinal product only the MEB agreed with the display of the OTC indication 'bij reisziekte' in the abbreviated indication.

- Vóór en tijdens de zwangerschap
- folic acid  
(in doses of 0.5 mg only)
- Bij pijn door overbelasting en blessure
- benzydamine hydrochloride  
(for dermal use only)
- Bij jeuk en pijn door insectensteken
- tripelenamine shydrochloride

## 7. List of abbreviated information on the indication area for traditional herbal medicinal products

Bij vastzittende hoest door taai slijm, prikkelhoest en/of keelpijn.\*

- Mixture of a water extract from the dried aerial parts of the flowering *Thymus vulgaris* L. and/or *Thymus zygis* L. ( thyme herb) and the water extract from *Althaea officinalis* (marshmallow root) )

- Water extract from the dried aerial parts of the flowering *Thymus vulgaris* L. and/or *Thymus zygis* L. (thyme herb)

Bij vastzittende hoest door taai slijm.\*

- *Hedera helix* L., folium (ivy leaf), ethanol extract
- Destilate of a mixture of rectified essential oil of eucalyptus oil, orange peel oil, myrtle oil and lemon oil (66-32-1-1)

Bij keelpijn en irritatie van mond en keel

- Mixture of ethanol extracts of *Echinacea purpurea* herba and radix and ethanol extract of *Salvia officinalis* folium

Bij nervositeit en spanning.\*

- Ethanol extract from the roots of *Valeriana officinalis* L (Valerian)

Bij blauwe plekken, en/of pijn door overbelasting of blessure.\*

- Ethanol extract from the fresh flowers of *Arnica montana* L (Arnica) (for dermal use only)

Bij moeilijke stoelgang

- Ispaghula Husk (*Anhydricum*)

\* Directly below the abbreviated statement on the indication area, the statement “Traditional herbal medicinal product” has to be added. The abbreviated information about the indication area and this statement form a single entity and should also be expressed as such on the packaging.