

LABELLING STANDARDS

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Outline

- Principles and Purposes of Labelling
- Labelling Requirements for Health Supplements (HS) and Traditional Medicines (TM)
- Types of Product Labels
- Examples of Good Labelling Practice

Principles and Purposes of Labelling

- The first point of interaction between a product and a consumer is the product label and it provides key information on the safe and proper use of the product.
- For consumers, product labels aid in product identification, selection and use and help them to make informed purchase decisions, when there is limited interaction with a healthcare professional.



Labelling Requirements for HS and TM

- Information must be in English. Information in other languages may be included and should be consistent with the English version.

1. Product Name (including Brand Name)	8. Country of Manufacture
2. Dosage Form	9. Name and Address of Local Importer (if applicable)
3. Name and Quantity of Active Ingredients	10. Contraindications, if any
4. Intended Purpose	11. Other warnings, if any
5. Dosage and Directions of Use	12. Storage Condition
6. Batch Number	13. Pack Size / Net Content
7. Expiry Date	

Product Name

- “**Product Name**” refers to the name given to a specific product to distinguish itself from other similar products in the market.
- A product may or may not have a brand name.
- “**Brand Name**” generally refers to a name given by the company or manufacturer to a product or range of products.
- E.g., **Anker Vitamin C**, **Anker Psyllium Husks Powder**, **Anker Joint Support**



Dosage Form, Dosage and Directions of Use

- “**Dosage Form**” refers to the final physical form of the product that contains the active ingredient(s) and may be used directly by the consumer, e.g., tablet, capsule, soft gel, liquid.
- The recommended **dosage and directions of use** provide information on the route of administration, dose, frequency, and duration of use (where applicable) for which the product is intended for use.



Naming of Active Ingredient

- “Active ingredient” refers to the ingredient that **contributes to the intended function of the product.**

Source	Naming Recommendation
1. Botanical or non-human animal materials	<ul style="list-style-type: none"> - Declared in scientific name followed by part constituting the active component, and type of preparation where applicable. - The use of the common / local name is optional. - E.g., <i>Eurycoma longifolia</i>, root, 200mg, extract 100:1 equivalent to 20,000mg of fresh root (Tongkat Ali) <i>Silybum marianum</i>, seed, 200mg, extract standardised to 80% silymarin (milk thistle)

Naming of Active Ingredient

Source	Naming Recommendation
2. Minerals	<ul style="list-style-type: none"> - For mineral supplements in the form of a salt, the strength of the element should be included. - E.g. Ferrous sulfate 50mg (providing 10mg elemental Iron); Ferrous fumarate 30mg (providing 10mg Iron); Zinc 7mg (provided in each Zinc Gluconate 50mg tablet)
3. Vitamins	<ul style="list-style-type: none"> - Common / chemical name could be used. - E.g. Vitamin C / Ascorbic acid 500mg; Vitamin A (as Retinyl Ascorbate) 300mcg

Inactive Ingredient

- “Inactive ingredient” refers to ingredients that:
 - a) Preserve the quality of the product
 - b) Enhance the keeping quality and stability of a product or to improve its organoleptic (e.g. taste, sight) properties
 - c) Provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of the product
- Inactive ingredients include:
 - Excipients
 - Flavouring and colouring agents
 - Preservatives

Inactive Ingredient

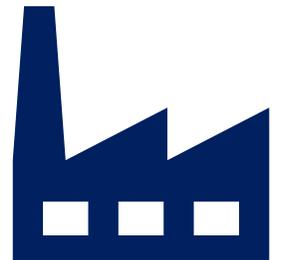
- Certain inactive substances that exhibit sensitising effects are required to be declared in medicinal products:
 - Benzoic acid
 - Sodium benzoate
 - Tartrazine
- Dealers are encouraged to review the safety of other sensitising agents that may be present in their products and declare their presence on the product label where necessary.

Intended Purpose

- “Intended Purpose” refers to a statement made on a product in relation to its indications, benefits or action.
 - E.g. supports cardiovascular health and circulation, relief of indigestion associated with hyperacidity or dyspepsia, traditionally used for relief of diarrhoea.
- Product type is not considered as intended purpose of the product.
 - E.g. Health Supplements, Traditional Medicines, Dietary Supplements, Liquid Supplements, Medicines.

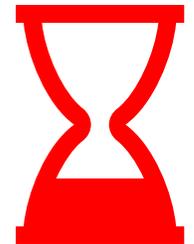
Batch Number

- **“Batch Number”** or **“Lot Number”** refers to a designation (in numbers, or letters, or combination of both) that identifies the product batch and allows traceability of the complete history of a specific product batch including all stages of production, control, distribution, and raw materials used.
- For clarity, the Batch Number should be preceded by title such as “Batch Number”, “Batch No.”, “BN”, “Lot Number” or “Lot No.”.



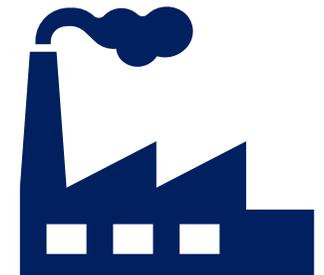
Expiry Date

- “**Expiry Date**” refers to the date assigned for each individual batch before which the batch still meets the required standard specifications for quality.
- Expiry date should be declared in month and year (e.g., Jan/2022, 01/2022) and preceded by title such as “Expiry date” or “EXP” to avoid ambiguity and confusion.



Country of Manufacture and Local Importer

- **“Country of Manufacture”** refers to the country where the product is manufactured.
- **“Name and Address of Local Importer”** refers to the complete name and address of the local importer of the product.
- If the local importer is also the distributor, the distributor information may be printed in place of the importer information.



Contraindications

- Contraindications declare situations where the product should not be used.
- E.g., This product is contraindicated for use in pregnancy.



Warnings

- Warnings are used to provide consumers with important information for their awareness before and during the use of the product.
- Warnings used should be simple, easy to understand and clear.
- Examples of warnings include:
 - Potential side effects
 - Presence of allergens / sensitising agents
 - Cautionary statements



Cautionary Statement for Certain Ingredients

- Products containing certain ingredients should include a statement declaring the potential risk or concerns associated with that ingredient on the product label.

Ingredient	Concern(s)	Cautionary Statement
1) <i>Cimicifuga racemosa</i> (black cohosh)	Known to cause liver side effects.	This product contains black cohosh which may harm the liver in some individuals.
2) Coenzyme Q10	Concomitant use with warfarin might reduce the anticoagulation effects of warfarin.	Do not take while on warfarin therapy without medical advice.
3) <i>Monascus purpureus</i> (red yeast rice)	Known to cause body and muscle aches.	This product contains naturally occurring lovastatin. Seek medical advice before use if you are already taking cholesterol lowering medicines. Discontinue use of the product if you experience muscle aches or weakness.

Cautionary Statement for TM making Symptomatic Relief Claims

- TM can make claims of symptomatic relief for non-serious medical conditions.
- To ensure that consumers do not delay in seeking appropriate treatment should their symptoms persist, TM with claims on symptomatic relief of non-serious medical conditions (e.g. cough, cold, diarrhoea) would be required to include the statement **“If symptoms persist, talk to your healthcare professional”**, printed on the product label.

Storage Condition

- The statement declares a condition to which the product should be stored properly to maintain the quality of the product throughout its declared shelf life.
- E.g., Store at room temperature away from direct sunlight; Store in a cool dry place; Store below 25 °C.



Pack Size or Net Content

- Pack size or net content refers to the amount of the product in a pack or container.
- This can be presented in absolute quantity (for solid dosage form) e.g., 30 capsules/container or net content (for liquid, powder, or semi-solid dosage forms), e.g., 500mL/bottle.



Types of Product Labels

Outer Label	Product packaging in which the immediate packaging of the finished product is contained, e.g. the carton box containing bottle, strips, blister packs.
Inner Label	Label affixed onto the primary container of the finished product, e.g. the immediate label affixed to a bottle or container where the finished product is contained.
Blister Label	Label affixed or printed on the strip or blister pack.
Small Label	Label with very limited space to display minimal information in the small container, e.g. label on ampoules or vials.

Types of Information Required for Labels

Information	Outer Label	Inner Label	Blister / Small Label	Leaflet, if any
1. Product Name including Brand Name	✓	✓	✓	✓
2. Dosage Form	✓	✓*	N/A***	✓
3. Name and Quantity of Active Ingredients	✓	✓	N/A***	✓
4. Intended Purpose	✓	✓	N/A***	✓
5. Dosage and Directions of Use	✓	✓	N/A***	✓
6. Batch Number	✓	✓	✓	N/A
7. Expiry Date	✓	✓	✓	N/A
8. Country of Manufacture	✓	✓*	N/A***	N/A
9. Name and Address of Local Importer	✓	✓*	N/A***	N/A
10. Contraindications, if any	✓	✓*	N/A***	✓
11. Other warnings, if any	✓**	✓*	N/A***	✓
12. Storage Condition	✓	✓*	N/A***	✓
13. Pack Size	✓	✓*	N/A***	✓

* May be omitted if the product is supplied with an outer label.

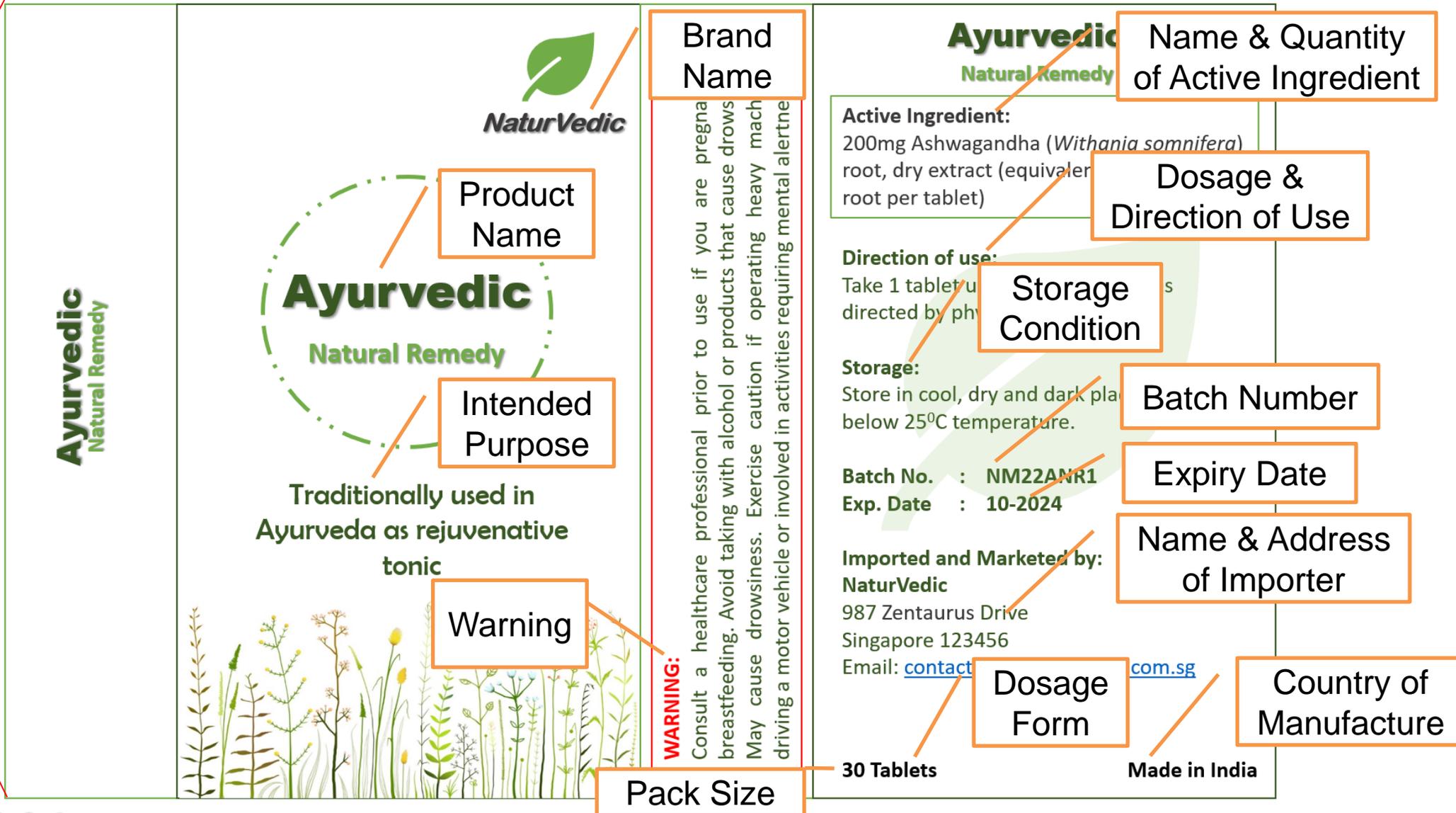
** May be omitted if the accompanying product leaflet provides this information.

*** The full product information should be displayed on the label of an accompanying outer carton box.

Example of Outer Label (Box)

<p>Natural source of edible soluble fibre</p> <p>Psyllium husks are a highly soluble source of dietary fibre rich in micronutrients. Psyllium husks are derived from the <i>Plantago ovata</i> plant. It is free from gluten and wheat, Anker's Organic Psyllium Husks Powder is an ideal source of fibre for those with allergies or those who need to avoid them.</p> <p>Suitable for vegetarians and vegans.</p> <p>Free from preservatives, fillers, gluten</p>	 <p>Anker</p> <p>Psyllium Husks Powder</p>  <p>Bowel Movement Support</p> <p>Helps to increase bowel movements, bulk and</p> <p>Made in USA</p>	<p>Each scoop contains: 100% Organic Psyllium husk (<i>Plantago ovata</i>, husk), dried.</p> <p>Also contains: Maltodextrin, citric acid, natural and artificial flavors, aspartame.</p> <p>Direction of use: Take one scoop (5g) twice a day. Mix with 150mL of water, stir briskly and drink immediately. Maintain adequate liquid intake.</p> <p>Storage: Store in cool, dry and dark place. Keep at below 25°C temperature.</p> <p>Imported and Marketed by:</p>	<p>Name & Quantity of Active Ingredient</p> <p>5 g</p> <p>Dosage & Direction of Use</p> <p>Batch Number</p> <p>Expiry Date</p> <p>Storage Condition</p> <p>Name & Address of Importer</p>
<p>WARNING: Consult a healthcare professional if symptoms worsen or if laxative effect does not occur within 7 days. If you experience chest pain, vomiting, swallowing and breathing difficulties, stop using this product.</p> <p>CONTRAINDICATION: Do not use this product if you have difficulty swallowing. Do not use this product if you have diabetes mellitus in which blood sugar is difficult to regulate.</p>	<p>500 g</p>	<p>Pack Size</p> <p>Email: contact_us@anker.com.sg</p>	

Example of Full Inner Label (Bottle)



Brand Name: NaturVedic

Product Name: Ayurvedic Natural Remedy

Intended Purpose: Traditionally used in Ayurveda as rejuvenative tonic

Warning: **WARNING:** Consult a healthcare professional prior to use if you are pregnant or breastfeeding. Avoid taking with alcohol or products that cause drowsiness. May cause drowsiness. Exercise caution if operating heavy machinery or driving a motor vehicle or involved in activities requiring mental alertness.

Pack Size: 30 Tablets

Active Ingredient: 200mg Ashwagandha (*Withania somnifera*) root, dry extract (equivalent to 200mg root per tablet)

Dosage & Direction of Use: **Direction of use:** Take 1 tablet twice daily after meals, as directed by physician.

Storage Condition: **Storage:** Store in cool, dry and dark place below 25°C temperature.

Batch Number: Batch No. : NM22ANR1

Expiry Date: Exp. Date : 10-2024

Name & Address of Importer: **Imported and Marketed by:** NaturVedic, 987 Zentaurus Drive, Singapore 123456, Email: contact@naturvedic.com.sg

Country of Manufacture: Made in India

Example of Simplified Inner Label (with Outer Box)



Brand Name: Mont-Étain

Name & Quantity of Active Ingredient: 1 capsule contains: Milk Thistle 200 mg
(*Silybum marianum*, seed)
Standardised to 80% silymarin

Dosage & Direction of Use:
Also contains: Dicalcium phosphate, cellulose, stearic acid, calcium silicate.
Direction of use: 2 capsules per day with a large glass of water during meals. Keep out of reach of children. Do not exceed the recommended daily dose.

Product Name: Liver Support

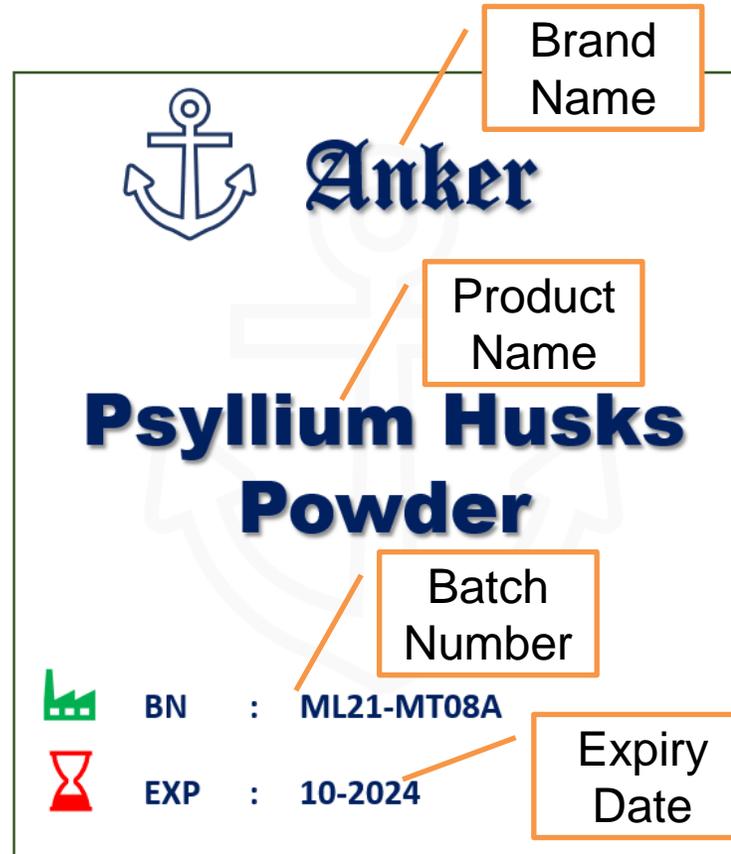
Intended Purpose: Contribute to maintenance of normal liver function

Batch Number: ML20-MT08A

Expiry Date: 10-2024



Example of Small Label (with Outer Label)



Examples of Good Labelling Practice

- **Font style and size**

- Use a font style that is not compressed, expanded, or decorative for key information.
 - E.g. Arial, Lucida Sans Unicode, Verdana
 - *Compressed, Expanded, Decorative*
- Use a font size that can be read easily by most users (e.g., elderly people, those with visual impairment) in different environments (e.g., indoor with low lighting).
 - Arial 24, Arial 14, Arial 9

Examples of Good Labelling Practice

- **Colour and contrast**

- The choice of colour combination on the product label should be carefully selected and applied to help consumers in choosing suitable products.
- Use colour to draw attention to important information on the product label.
- Select proper colour contrast between text and background to ensure legibility of text, e.g. dark text on pale background.

Label 01

Label 02

Label 03

- Avoid using colour combination that may be challenging to distinguish for individuals with colour blindness, e.g. red and green, colour with different intensities, etc.

Label 04

Label 05

Label 06

Examples of Good Labelling Practice

- **Clear overall presentation**
 - The overall presentation should be aligned to that intended as a health supplement or traditional medicine and not food product, e.g., milk, botanical beverage or fruit juice, cookies, coffee or tea, snacks
- **Illustrative and photographic representation**
 - The use of any pictorial or illustration to support the physical attractiveness of the product should not be misleading and inappropriate.

Conclusion

- It is important that a product is appropriately labelled to provide key information to consumers on the safe and proper use of a health product.
- Improperly or inadequately labelled products may lead to misinterpretation and misuse of the product resulting in undesirable effects on the consumers.