

New labelling requirements for excipients (the inactive ingredients in a medicine)

This leaflet is about new labelling requirements for certain excipients in medicines. This leaflet does not replace talking with your doctor, pharmacist or other health professional about your medicine.

What are excipients?

Medicines contain active and inactive ingredients (excipients). The active ingredient makes the medicine do what it claims, for example, paracetamol for pain relief. Examples of excipients added to medicines include:

- oils or alcohol to help the active ingredient dissolve
- fillers or binding ingredients to make a tablet's shape and size
- sweeteners to improve the taste
- preservatives to make the medicine last longer.

Some people may wish to avoid some excipients

Some excipients in medicines can make some people with allergies, intolerances or medical conditions unwell. For example, people with:

- anaphylaxis (a life-threatening allergic reaction) to peanuts, soya or sesame should avoid medicines containing peanut oil (also called Arachis oil), soya or sesame oil
- coeliac disease should avoid gluten
- phenylketonuria should avoid aspartame and phenylalanine
- galactosemia or lactose intolerance should avoid lactose
- diabetes should limit the amount of sugar they eat or drink.

Some excipients are made from animal products, which vegetarians, vegans or people of a particular faith may want to avoid.

Normally, there is only a tiny amount of an excipient in a medicine. **Check with your doctor or pharmacist** if you have concerns about the contents of your medicine.

New labelling requirements

From 1 March 2024, there are new labelling requirements for the excipients listed in Table 1 on the next page. If a medicine contains an excipient listed in the table, the pharmaceutical company will be required to add a warning statement to the medicine box or packaging.

You can also search the Label Statements Database to find out if a particular excipient needs to be declared and to see the warning statement: medsafe.govt.nz/regulatory/labelling.asp

Table 1: Excipients (inactive ingredients) that must be declared on medicine labels from 1 March 2024*

Antibiotics	Lactose	Sodium salts
Aspartame	Milk/milk products	Sorbic acid/sorbic acid salts
Benzoates	Peanuts/peanut products	Soya bean/soya bean products
Crustacea/crustacean products	Phenylalanine	Sucralose
Egg/egg products	Pollen	Sugar alcohols
Ethanol	Potassium salts	Sugars
Fish/fish products	Propolis	Sulphites
Galactose	Royal jelly	Tartrazine
Gluten	Saccharin	Tree nuts/tree nut products
Hydroxybenzoic acid esters	Sesame/sesame seed products	

* For medicines released to the New Zealand market after 1 March 2024. Medicines released before this date are not required to declare the excipient on the label. Check with your doctor, pharmacist, other health professional or the pharmaceutical company for more information.

How do I find out which excipients are in my medicine?

There are several ways to find out which excipients are in your medicine. Your doctor, pharmacist or other health professional will be able to help.

Medicine box or packaging

From 1 March 2024, there will be a warning statement on the medicine box or packaging for the excipients listed in Table 1. If the medicine container is small, the warning statement will be on the information leaflet inside the container instead.

Consumer medicine information (CMI)

If there is a CMI for your medicine, excipients are listed in the 'Ingredients' section near the end of the document. You can search for the CMI on the Medsafe website:

medsafe.govt.nz/Medicines/infoSearch.asp

Data sheet (prescribing information)

The medicine data sheet (prescribing information) lists the excipients in the 'Pharmaceutical Particulars' section near the end of the document. You can search for the data sheet on the Medsafe website:

medsafe.govt.nz/Medicines/infoSearch.asp

Product/Application search

If your medicine does not have a CMI or a data sheet, you can use Medsafe's Product/Application search:

medsafe.govt.nz/regulatory/dbsearch.asp

- Enter the medicine's brand name in the 'Trade name' box. Click on the relevant search result to view the excipients in that medicine.
- To find out which medicines contain any excipient – enter the excipient in the 'Ingredient' box. The search results list all the medicines containing that excipient.

Contact the pharmaceutical company

There may be some information about your medicine that only the pharmaceutical company can provide. This may include:

- ingredients within a flavour or colour
- manufacturing impurities or contaminants
- components of an ingredient (such as caffeine in a natural health product)
- the source of an ingredient (such as whether it is of animal origin).

Look for the company contact details on the medicine packaging, or in the data sheet, CMI or Product/Application search.

More information

- **Healthify** – 'Excipients in medicines', available at: healthify.nz/medicines-a-z/e/excipients-in-medicines/
- **Allergy New Zealand** – 'Food allergy or food intolerance', available at: allergy.org.nz/conditions/food-allergies/allergy-vs-intolerance/