



Australian Government

Department of Health

Therapeutic Goods Administration

Updating medicine ingredient names

International harmonisation of ingredient names

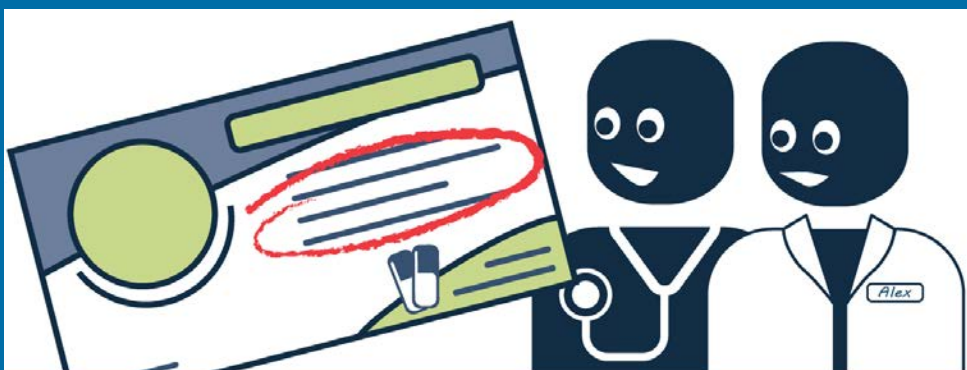
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ARCS webinar
10 June 2016

TGA Health Safety
Regulation



Overview



Be informed

Some medicine ingredient names are changing

- Ingredient terminology
- What are the changes?
- Transition period



Ingredient terminology



Australian Approved Names

VS

ingredient names used
internationally

The World Health Organization's
International Nonproprietary Names (INN)
are the gold standard for medicine
ingredient names



What are the changes?

Some changes are minor

Spelling

Amoxyicillin



amoxiicillin

Spacing

cyanocobalamin(57Co)



cyanocobalamin (57Co)

Hydration state

carbidopa anhydrous



carbidopa



What are the changes?

Some changes are more significant → Dual labelling

lignocaine



lidocaine (lignocaine)

amethocaine



tetracaine
(amethocaine)

colaspase



asparaginase
(colaspase)



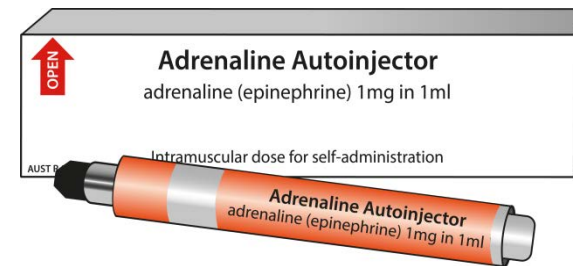
Adrenaline and noradrenaline

INNs: Epinephrine and norepinephrine

Adrenaline and noradrenaline continue to be the names used in Australia.

In addition to the approved ingredient name, the INN will also be required on:

- Medicine labels
- Product information
- Consumer Medicine Information



This is consistent with the approach taken in the UK



Transition period

Names within ARTG entries

Updated by TGA



Completed April 2016

Existing products

Changes to labels and documents where an AAN is required



Transition until April 2020
Dual labelling until April 2023

New products

Must use new AANs on labels and documents where an AAN is required



From time of
registration/listing

Trade names

Can update voluntarily



No fee until April 2020



Informing health professionals and consumers



TGA working with

- Industry representatives
- Health professional groups
- Medication software vendors

Key issue

Timing of label changes



Further information

TGA website

- Full list of name changes
- Information for sponsors
- Information on adrenaline and noradrenaline changes
- Printable information materials

The screenshot shows the TGA website's 'Industry' section. The page title is 'Updating medicine ingredient names' with a date of 17 March 2016. The breadcrumb trail is 'Home > Industry > Regulation basics > Labelling & packaging'. The page features two main icons: 'Some medicine ingredient names are changing' and 'Gradual 4 year transition period for existing products'. A 'Related information' box contains links to 'Changes to adrenaline and noradrenaline labels' and 'List of affected ingredients'. The main text explains that some medicine ingredient names in Australia have become out of date and are being updated to align with international names. A 'What is happening' section lists key points: the transition period starts in April 2020, new names will appear on shelves, names may change, and prescribers should be careful.

Industry

- Regulation basics
 - How therapeutic goods are regulated in Australia
 - Australian Register of Therapeutic Goods
 - Industry educational materials
 - Legislation & legislative instruments
 - Advertising therapeutic goods
 - Labelling & packaging**
 - Import and export
 - Clinical trials
 - Cosmetics
 - Safety information for industry
- Prescription medicines
- Over-the-counter medicines
- Complementary medicines
- Sunscreens
- Medical devices & IVDs
- Biologicals
- Blood & tissues
- Other therapeutic goods
- Manufacturing therapeutic goods
- Scheduling of medicines & poisons

Updating medicine ingredient names

17 March 2016

Some medicine ingredient names are changing

Gradual 4 year transition period for existing products

Related information

- [Changes to adrenaline and noradrenaline labels](#)
- [List of affected ingredients](#)

In different countries, different names are used to describe the same medicinal ingredient.

Over the years, some medicine ingredient names in Australia have become out of date. This can be confusing for Australian consumers and healthcare professionals who travel internationally, as well as other people like doctors who have trained overseas or people trying to access medicine information online.

We are updating some medicine ingredient names used in Australia to align with names used internationally. This has been done by a number of other countries over the years, including the United Kingdom in 2003 and New Zealand in 2008.

Not all medicine ingredient names are changing. A list of medicine ingredient names that will be changing is available at: [List of affected ingredients](#).

What is happening

- The four year transition period for these changes has started and will end in April 2020.
- Medicines with labels using the new ingredient names will gradually start to appear on shelves.
- Although the name of the ingredient may have changed, the medicine is the same.
- Take care when prescribing, dispensing and administering medicines to make sure that the right product is selected.



Discussion and questions



Keep an eye on safety
as medicine ingredient names change



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