



Generic prescription medicines

Information for consumers

What is a generic medicine?

A generic medicine is an additional brand of an existing medicine. It contains the same active ingredient (the chemical that makes the medicine work) as the existing medicine.

Apart from containing the same active ingredient, generic brands also have to be 'bioequivalent'. That is, if you take the same dose of a generic medicine as an existing medicine, the same amount of active ingredient is absorbed by your body over the same period of time.

Bioequivalence is demonstrated by conducting a 'bioavailability' study in which volunteers (usually healthy) are given the original medicine and, on a separate day, the generic medicine. Blood samples are taken at different times, and the rate and extent of absorption of the active ingredient into the blood is compared between the generic and existing medicines.

Generic medicine containing the same active ingredient can be manufactured and sold by other companies once the patent for the existing brand has expired.

What we do when we authorise a generic prescription medicine for supply?

A generic prescription medicine is only allowed to be supplied in Australia if we consider that the evidence shows that the generic medicine is bioequivalent to the original medicine.

We look at the:

- consistency and quality of the manufacturing process for the medicine
- the quality of the ingredients and the final product

- the combination of ingredients used to make the final medicine product
- the safety information obtained from laboratory studies and clinical trials on the original medicine.

We also look at how long the active ingredient remains stable at particular temperatures—this is used to determine shelf life and recommended storage conditions for the medicine.

If necessary, we also make available information on the use of the generic prescription medicine, for example, warnings about using the product and drinking alcohol. These can be found in the Product Information and the Consumer Medicines Information, available from pharmacists and the TGA website.

Are generic prescription medicines effective?

A generic prescription medicine works in the same way as the existing medicine. What matters is the active ingredient, which is the same in the generic brands and the existing brand.

All medicines will have the same potential health benefits, and the same potential side effects. Some active ingredients are only effective for some patients and this will be the case whether you use the original or a generic medicine.



How do I know that generic prescription medicines are as safe as possible?

Generic prescription medicines meet the same standards of quality, safety and effectiveness as the original brand.

As with all medicines and medical devices the TGA continually monitors safety once they are on the market.

If you suspect you have experienced a problem with any medicine, including a generic medicine, please **report it to the TGA** <<http://www.tga.gov.au/safety/problem.htm#medicine>>

What about the difference in cost between generic prescription medicines and the original version?

The cost of a medicine is not considered by the TGA when deciding whether the medicine can be supplied in Australia. Our role is to ensure that generic prescription medicines are made to the same standard as original medicines.

All brands of the same medicine, regardless of price, have the same active ingredient and have been authorised for supply in Australia.

However, generic prescription medicines may be more affordable for consumers. You can ask your doctor to prescribe a generic medicine, or ask your pharmacist if they are able to supply you with a more affordable brand of the same medicine.

If they are the same, why do they sometimes look or taste different?

Although they work the same and have the same active ingredient, generic prescription medicines may not look the same as the original medicine. All medicines contain inactive ingredients (excipients) as well as active ingredient(s), and these inactive ingredients are often different in the generic medicine.

Inactive ingredients have a number of different functions, including providing colour and taste. Generic tablets or capsules can also be a different size or shape from the original medicine.

Please let your doctor or pharmacist know if you have any allergies – just in case the generic medicine contains the substances you are allergic to in the inactive ingredients.

More **information about inactive ingredients** is available from the NPS Medicinewise website.

You can find a list of the inactive ingredients in the **Consumer Medicine Information** (CMI) for most prescription medicines, which you can obtain from your pharmacist or **download from the TGA website**.

Is every prescription medicine available as a generic version?

No. The original medicine may be the only version available because the medicine is relatively new in the market.

Do I have to accept a generic medicine if it is offered?

No, you do not have to accept any medicine if it is offered to you; the choice is yours. Ask your GP or pharmacist if you have any questions or concerns about switching between brands of medicine.

There may be times when your doctor recommends you stick with one particular brand.

Read more about **when a different brand may not be an option** on the **NPS Medicinewise** website.

Links

Pharmaceutical Benefits Scheme <<http://www.pbs.gov.au/pbs/home>>

Good Manufacturing Practice <<http://www.tga.gov.au/industry/manuf-gmp-tg.htm>>

Report a problem to the TGA <<http://www.tga.gov.au/safety/problem.htm#medicine>>

NPS Medicinewise <<http://www.nps.org.au/topics/how-to-be-medicinewise/buying-medicines/generic-medicine-brands/other-ingredients-in-medicines>>

TGA Consumer Medicines Information <<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>>

NPS Medicine finder <<http://www.nps.org.au/medicines>>

