ACTIVE INGREDIENT PRESCRIBING: ALL YOU NEED TO KNOW

The way medicine information looks on your prescription from your doctor is changing. The change is part of an Australian Government initiative, and means most Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS) prescription medicines will be prescribed by their active ingredient rather than their brand name.

What is an active ingredient?

Active ingredients are what make a medicine work. A brand name is the name given to a medicine by its manufacturer.

There are a lot of medicines that contain the same active ingredient but have different brand names. This is not unique to medicines. Our supermarkets are filled with products that are the same on the inside, but have different brand names.

All medicines should have their active ingredients listed on the packaging or container they come in. The medicine packaging also shows how much of the active ingredient is in that particular formulation. This is the strength of the medicine. Some medicines can have the same brand name, but come in different strengths of an active ingredient, so they can be used for different conditions or by people in different age groups (eg, babies, infants, adults).

Occasionally, a medicine has more than one active ingredient. If so, the name of each active ingredient is shown on the packaging and pharmacy dispensing label.

About generic medicines

When a pharmaceutical company develops a new active ingredient, it is granted a patent. This means that for a period of time no other company can manufacture and sell a medicine containing the same active ingredient.

This first medicine to come onto the market is sometimes called the **originator** brand.

Once a patent expires, other companies can develop their own versions of the medicine. These are known as **generic medicines**. Their active ingredient is the same as the originator brand, but the newer medicines are marketed under different brand names.

Due to trademark regulations, the packaging of generic medicines and sometimes the actual medicine itself (the pill, tablet, capsule etc) are made to look different from the originator brand.

What difference will using a generic medicine make?

All medicines sold in Australia must be approved by the government through the Therapeutic Goods Administration (TGA). The TGA requires generic medicines to meet the same strict standards of quality, safety and effectiveness as the original brand. A generic medicine must also have evidence to show it will work in the body in the same way as the original brand medicine. This is called being bioequivalent.

So for most medicines, the benefits and side effects will be the same for the original and generic versions of that active ingredient.

For consumers, the main difference between generic and brand medicines is likely to be how much they have to pay for the medicine. Generics are less expensive to make, and that means they tend to be less expensive to buy.

Unless your health professional has prescribed a specific brand of medicine for you, it's your choice whether you use a generic medicine or the original brand.

Be medicinewise about your choices by discussing your options with your prescriber or pharmacist.

What is active ingredient prescribing?

PBS and RPBS prescriptions now need to include information about the active ingredients in each medicine. The inclusion of active ingredients on prescriptions will be mandatory from 1 February 2021. If a prescriber would also like to include the medicine brand name, it will appear after the active ingredient information.

This latest initiative supports other government activities that help encourage general awareness around active ingredients, such as the TGA initiative to make active ingredient names on medicine packaging easier to locate and read.

All these actions mean that it will be easier for you and your prescriber or pharmacist to talk about your options for different medicines that contain the same active ingredient. You may be able to choose a generic or biosimilar medicine, which may be cheaper than a brand name medicine.

The changes will also support greater consistency around how people see medicines information. This can lead to safer and more appropriate use of medicines by making it easier to:

- check if you are taking the same active ingredient in more than one prescription medicine – to prevent accidental double dosing
- check that you're not taking an active ingredient you're allergic to
- check that the active ingredient can be taken with medicines that have other active ingredients
- identify suitable alternatives to your usual medicines when travelling overseas.

Sometimes it is important to stay with the same brand of medicine. Health professionals can still prescribe a specific brand of medicine if they think it's necessary.

Some prescription medicines have more than one active ingredient, and these will all be listed on the prescription (except as explained below).

The new regulations do not apply to:

- handwritten prescriptions
- paper-based medicine charts in the residential aged care sector
- medicines that contain four or more active ingredients
- medicines that have been excluded to protect patient safety or where it is impractical to prescribe the medicine by active ingredient.

When to keep taking the original brand

Although you can often save money by choosing a generic medicine, some people should not change brands. There are also some situations where your doctor may prescribe a specific brand of medicine because they believe it is the one that best meets your clinical needs.

If your doctor decides it is necessary for you to stay with a specific brand, they will need to add the brand name and tick the 'Brand substitution not permitted' box on your prescription.

Other ingredients in medicines

As well as the active ingredient, medicines contain other ingredients known as inactive ingredients or excipients.

The active ingredient is important as this is the chemical that makes the medicine work, but inactive ingredients are needed as part of the manufacturing process. An inactive ingredient may be included:

- as a filler if the quantity of active ingredient is very small
- to stabilise the active ingredient so that it stays effective for longer
- to help the active ingredient be absorbed more effectively by the body
- as a binder to hold all the ingredients together
- to sweeten or flavour the medicine to make it easier to take
- to coat tablets or capsules so that they're easier to swallow.

For most people, the inactive ingredients won't matter. However, if you have particular allergies or intolerances, or choose to avoid certain substances for cultural or medical reasons, you may need to know what excipients are in your medicine. Ingredients such as lactose, gluten, sugar, preservatives and dyes might matter to you. If this is the case, be medicinewise and check with your pharmacist or doctor before you choose a different medicine brand.

What support is available for prescribers?

To help prescribers and pharmacists stay up to date with the new regulations and what they mean for their practices and patients, the Department of Health has worked with the Australian Commission on Safety and Quality in Health Care to develop a range of support materials. This information explains when prescribers might want to consider including brand names on prescriptions, and how health professionals can protect patient safety.

The Department of Health has also prepared information about active ingredient prescribing, including a fact sheet for health professionals.

NPS MedicineWise also has information for health professionals.

Where can I find out more?

- For more information about Active Ingredient Prescribing send your questions to AIPrescribing@health.gov.au
- Find information on medicines by active ingredient or brand name using Medicine Finder.
- For questions about prescription, over-the-counter and complementary medicines, talk to a health professional through **Medicines Line** (**1300 MEDICINE**)(**1300 633 424**).
- Keep track of medicines and access important health info anytime and anywhere, especially in emergencies, using the MedicineWise app.

nps.org.au

Level 7/418A Elizabeth Street Surry Hills NSW 2010
PO Box 1147 Strawberry Hills NSW 2012
02 8217 8700 02 9211 7578 info@nps.org.au

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