What are generic drugs?
Used in relation to medication, the term ‘generic’ refers to:
- A drug’s chemical name, rather than the brand name under which it is sold
- Any drug marketed under its chemical name without advertising

Lamotrigine is one example of the chemical (generic) name of an antiepileptic drug (AED). It is marketed by some companies under its generic name and by others under its brand name, Lamictal.

Generic drugs are less expensive than brand-name drugs although they are almost chemically identical, and meet Australian standards for safety and effectiveness.

Why are they needed?
The world has long recognised the danger of granting patent or copyright to drug companies. Since 1994, to prevent companies monopolising the production of life-saving medications (such as amoxicillin, or Amoxil, for pneumonia) and setting prohibitively high prices, drugs have a patent life of 12 to 17 years. This allows other manufacturers to enter the market and sell cheaper drugs because they can skip the expense of research and development.

Generic vs brand medications
Generic drugs are not exactly the same as the original preparation. But by definition, they are close enough. For most people that will be appropriate.

New, generic drugs undergo strict tests to establish that they are chemically close to the brand drug being duplicated and fulfil criteria set by government. The drugs are compared by studies on volunteers who first take the generic drug then the original. Their blood levels are measured to check drug concentrations of each preparation and see if they match over time.

Drugs are absorbed until they reach a maximal concentration, then the body starts excreting them by various mechanisms through the liver and the kidneys, which of course is why doctors usually ask patients to take tablets once or twice daily.

Volunteers are examined on the same day, using the same tests and the same drug, and although individual bodies will handle drugs very differently volunteers must arrive in the same condition every time. The data is collated and a report is written to government saying whether the generic drug meets the criteria by closely matching the original drug. Regulations state that the generic drug absorption must be within 80% to 120% of the original. In practice, however, brand and generic drugs will vary by only 3% to 4%. Though slight, this is still a variation.

Can I take generic drugs?
Prescribing drugs to patients with seizures normally involves a lot of trial and error to find the right combination. Doctors are guided by:
1. The recommended dose for that particular drug
2. Blood tests that measure the drug’s concentration in your bloodstream
3. Clinical response

Doctors will consider a patient’s clinical response – if seizures reduce or cease with minimal side-effects. Doses can vary widely between individuals, and we try to use the lowest effective amount.
Generic drug use in epilepsy – Epilepsy Society of Australia Position Statement

“Generic preparations of several antiepileptic drugs are available to patients in Australia. Retrospective studies and case reports indicate that there is a small risk of loss of seizure control or toxicity if interchange of generic and innovator antiepileptic drug occurs. Patients with epilepsy should first obtain the advice of their treating doctor before having the preparation of antiepileptic drug interchanged.”

For the full statement see http://www.epilepsy-society.org.au/pages/guidelines2.php

Is brand substitution safe for people with epilepsy?

Substitution refers to a change of drugs from one product to another, whether original or generic to a new brand. Three outcomes are possible: 1) the blood concentration of the drug could increase, 2) it could fall, or 3) it could stay the same.

Most people experience no change at all. But if blood concentrations do vary slightly and you’ve been taking just the right dose, there might be adverse effects. While there is no clinical proof of impacts, indirect evidence suggests AED substitution is not a good idea.

The first data on impacts associated with substitution originated in England, where many patients were switched to generic drugs as they became available. In a survey a number of respondents indicated feeling worse after they became available. In a survey a number of respondents indicated feeling worse after they became available, where other medical or psychological explanations were identified.

Delving deeper, researchers found little increase among patients who switched once. But if in a month they changed from one brand to another, then yet another, that patient had a 60% increased risk of hospitalisation.

Guidelines for substitution

Many international bodies, including the Epilepsy Society of Australia (ESA), have published written guidelines (see above). This recommends substituting AEDs only with your doctor’s advice. Generally the answer is yes. Some patients may even be prescribed a generic drug initially.

Reliable drugs taken reliably

Normally with seizure disorders, the essence is to use reliable drugs, and take them reliably; take them regularly as prescribed.

This article was based on a speech by Dr Dan McLaughlin, who is a Brisbane-based neurologist and a 2010 committee member of the Epilepsy Society of Australia.

Experience after switching brands of anticonvulsant - Figure 1

From “Generic Prescribing for Epilepsy. Is it Safe?”, a UK study involving 251 patients who reported taking a different pharmaceutical manufacturer’s supply of the same antiepileptic drug.

- Sodium valproate n = 100
- Carbamazepine n = 84
- Phenytoin n = 57
- Total n = 251

Problems experienced (% of total switches)

- Validated = increase in seizure frequency or side-effects with no other identifiable medical or psychological causes.
- Unproven = increase in seizure frequency or side-effects where other medical or psychological explanations were identified e.g. confusion, worry, stress.
- Incomplete = increase in seizure frequency or side-effects, but no response to follow-up approaches.

Fast facts – Generic drugs

Sometimes your chemist will offer you generic drugs. These vary slightly from brand medications. The name, packaging and tablets are different, and they are often a little cheaper.

Impacts

Switching between brands may cause problems with your epilepsy including:

- More seizures
- More severe seizures
- Seizures after a long period of remission
- More side-effects
- Different side-effects

Tips to remember

1. If it works, don’t switch

If your seizures are controlled with your current medication, DO NOT change it without talking with your neurologist or prescribing doctor – even if the pharmacist says it’s okay.

2. Take note of your brand

Keep a written record of your usual medication. Take the packet to the chemist when getting your script filled.

3. Check the packet

Your doctor can tick a box on your prescription to ensure you are not given any other version of your medication. If this box is ticked, point it out to the pharmacist.

4. Check the packet

Check the packaging and brand name against what you usually use before you leave the chemist. If it doesn’t match, ask for it to be changed.

5. Consider the real cost

If your pharmacist suggests that switching to a ‘generic’ can save you money, consider if the small saving is worth the cost of more problems with your epilepsy. Feel free to politely refuse and insist on your usual medication.

6. Educate

Let the pharmacist know about problems that can occur if you switch brands.

7. Follow doctor’s advice

Never switch a brand of medication you have been prescribed without speaking to your neurologist or prescribing doctor.