Generic and branded ASMs



Anti-seizure medications

Anti-seizure medications (ASMs) aim to prevent seizures from happening. To be most effective, they need to be taken every day, at around the same time. They are often taken for many years, unlike a short course of treatment (such as antibiotics).

Visit epilepsysociety.org.uk/medication-epilepsy

What are branded drugs?

'Branded' drugs are the original version of a drug produced by the drug (pharmaceutical) company which developed the drug. To start with, only the company that developed the drug can produce it. This is called being 'on patent' and the drug will have a brand name that only that company can use. For example, Tegretol is the brand name of the ASM carbamazepine.

What are generic drugs?

All drugs have an 'active ingredient' (the part of the drug that treats the condition you take it for). This ingredient is often referred to as the 'generic' name.

Once a branded drug has been on the market for a number of years, other companies are allowed to start producing their own version of the drug (after it comes 'off patent').

These other companies might call their version of the drug by just the generic name, such as 'carbamazepine', or they might give their version another name (sometimes called a 'branded generic'), such as 'Carbagen'.

Several drug companies might produce their own versions of a generic drug, but they will all contain the same active ingredient.

Different versions of ASMs will look different

Each company's version of a drug will usually look different, so that you can tell different versions apart, and you can recognise a particular drug from a specific drug company. The differences include the size, colour and any writing on the tablets or capsules themselves. The packaging will also look different.

If two different ASMs have the same generic name, are they exactly the same?

Although ASMs with the same generic name have the same active ingredient, this does not mean that they are exactly the same. This is because drugs contain other ingredients, such as colouring and binding agents (ingredients that hold the tablet together), which can be different from one version to another. In some cases, these other ingredients might affect how the drug is absorbed in the body, which could affect how well the active ingredient works in the brain to stop seizures.

How different are generic drugs with the same name? When a new generic version of a drug is developed, it has to be shown to be 'bioequivalent' (have a similar absorption and distribution), within a certain range, to the original 'on patent' brand.

This means they have to be 'similar enough' to the original in how they are absorbed and distributed in the body and therefore the amount of active ingredient that gets to the brain. However, a generic version only has to compare in this way to the brand version, not to other generic versions.

So, two generic versions might have greater differences between them, in the way they are absorbed and distributed, than the differences between a generic and a brand version.

Which is better, branded or generic?

A 'brand' version of an ASM is not 'better' or 'worse' than a generic version of that drug. The important thing is that you and your doctors find a version of a drug which suits you, and you take this version consistently. 'Consistency of supply' means getting the same version of a drug with every prescription.

Guidance on prescribing

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance on prescribing anti-seizure medication. They say that certain ASMs must be prescribed with the same version, and for other ASMs this is less important.

Getting the same version of ASMs each time may contribute to how well the drug works for that person. Switching could cause confusion, anxiety, side effects or a breakthrough seizure for some people.

Epilepsy Society Helpline 01494 601400 helpline@epilepsysociety.org.uk Confidential, national call rate. Information and emotional support. This aims to help doctors decide whether they should prescribe a particular version.

The guidance divides ASMs into three categories according to the importance of maintaining a consistent supply and depending on whether there is considered to be a risk of problems if switching between different versions.

Category 1

Phenytoin, carbamazepine, phenobarbital and primidone. Specific measures are necessary to ensure consistent supply of a particular product. This means that individuals should not be switched between versions of these ASMs, but should always kept on the same version.

Category 2

Sodium valproate, lamotrigine, perampanel, retigabine, rufinamide, clobazam, clonazepam, oxcarbazepine, eslicarbazepine acetate, topiramate and zonisamide. The need for continued supply of a particular product should be based on 'clinical judgement' (the doctor's judgement of the risk of problems), and in consultation with the individual.

This means that a doctor should decide, with the individual, whether it is important to always stay on the same version or whether it is ok to switch between different versions.

Category 3

Levetiracetam, lacosamide, tiagabine, gabapentin, pregabalin, ethosuximide, brivaracetam and vigabatrin. No specific measures are normally required and these ASMs can be prescribed generically. This means that individuals can be switched between different versions of their ASMs.

The guidance states that in some cases consistency of supply is important "where the consequence of therapeutic failure or toxicity might have serious clinical consequences". This means there is a risk that switching between different versions might mean that the drugs don't work to control seizures, or they cause toxic side effects, and this would have a serious impact on the individual.

The guidance also says that, in some cases, consistency of supply is important when there are "specific concerns such as patient anxiety, and risk of confusion or dosing errors". This means that when someone is very worried about switching between ASMs, or switching might cause confusion or result in someone not taking the right dose, their doctor might want to ensure consistency of supply.

The guidance also tells doctors how they can write prescriptions to ensure consistency of supply.

For example, they can put a brand name (if the person is taking a branded ASM) or they can put the generic name and the name of the pharmaceutical company (sometimes referred to as the Marketing Authorisation Holder or MAH) to ensure the correct version is dispensed at the pharmacy.

Visit gov.uk/drug-safety-update/antiepileptic-drugsupdated-advice-on-switching-between-differentmanufacturers-products

Concerns about switching between drugs

There are several reasons why switching between different versions of ASMs may be a problem for some people.

- Switching from one version of a drug to another might mean that higher, or lower, amounts of active ingredients reach the brain. If the level is lower in one version than another, seizures could happen. If the level is higher, this could cause side effects.
- People with memory problems or confusion may not remember what their ASMs look like, and so may find it hard to check that they are getting the same medication each time. Or they may get confused about what medication they take, especially if it has changed in colour or size. This could lead to errors in prescribing or taking ASMs.
- Being given different versions of ASMs could cause anxiety, which is a common trigger for seizures.

What can I do if my ASMs have been switched?

Talk to your neurologist

If you have a neurologist, you can talk to them about your concerns. If they agree that you need to always have the same version of ASMs, you can ask them to pass this information on to your GP, with instructions on how to prescribe the same version each time.

Talk to your GP

Your GP is usually responsible for your prescriptions. If you are taking a brand version of your ASM, you can ask them to write the brand name on your prescription. If you take a generic version, ask them to write the name of the manufacturer, with the generic name.

Talk to your pharmacist

If you use the same pharmacy regularly, your pharmacist may keep a record of what medication you take. They might be able to make a note to get the same version of your ASMs for you each time.

If pharmacists don't have your usual version in stock, you can ask for your prescription back, and take it to another pharmacy. Check that you have your correct ASMs while you are at the counter, as they won't be able to change it after you leave the pharmacy.

Visit epilepsysociety.org.uk/making-mostyour-pharmacist

You may want to download this factsheet from our website to give to your GP, neurologist or pharmacist. You can also call our helpline for a copy.

Get to know your medication

It can be a good idea to keep a list of your ASMs: the generic name, any brand name, and the manufacturer's name. You could also make a note of the colour and shape, to help you recognise it. This might help you to check your prescription from the doctor, or from the pharmacy. You could also use your phone to take photos of your medication.

Helping you to take your ASMs

Other things that might help you to take your ASMs, and to get the best effect from them, include the following.

- A drug wallet (pill box) can help you to keep track of when you have taken your medication.
 Visit livingmadeeasy.org.uk for drug wallets and medication aids.
- A seizure diary can help to keep track of your seizures and see if there is any pattern as to when they happen. Diaries can also help your doctors to see whether your medication is working.

Contact our helpline for a free seizure diary.

- The patient information leaflet that comes with your ASMs states what to do if you have any problems with your ASMs, such as missing a dose or being sick.
- If you are prescribed other medication, your doctor or pharmacist can check whether this medication could affect your ASMs, or vice versa.

For a printed copy of this information contact our helpline.

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