

Reporting problems with your epilepsy medications



What should you do if you have an adverse reaction to your anti-epileptic medication or experience a side effect which isn't listed in the patient information leaflet that comes with your drugs? Reporting your problem to the Yellow Card Scheme is an easy way to share your experience and help to ensure the continued safety of medicines in the future

All medicines have the potential to cause side effects. As anyone who takes anti-epileptic medication will know, there is often a trade off between seizure control and side effects. These can range from dizziness and nausea to depression and cognitive impairment.

The packaging for your medication will include a patient information leaflet listing all the possible known side effects for that particular drug. This does not mean that you will necessarily experience those side effects. It just means they are a possibility and of course you should always discuss any side effects with your GP, neurologist or epilepsy specialist nurse. It could be that the dose of medication you have been prescribed is too high and that if reduced, the side effects will disappear or lessen.

However, occasionally you may experience a reaction or side effect that is not listed. As with all side effects, this should always be reported to your healthcare professional but you could also report it via the Yellow Card Scheme.

The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines. MHRA is the Medicines and Healthcare Products Regulatory Agency which is responsible for regulating all medicines and medical devices in the UK.

Before a medicine is licensed, it must undergo a series of clinical trials.

These are carried out in a relatively small number of patients – on average 1,500 for a new medicine. They are also conducted under very strict conditions. A medicine will only be given a licence if its benefits are thought to outweigh, or justify, its risks.

In everyday life, medicines will not be used under trial conditions and may be used by millions of patients of all ages, who may also be taking other medicines and who will undoubtedly have varied lifestyles.

Although clinical trials may identify the more common and predictable side effects of medicines, rarer side effects may only be highlighted once the medicine is used by a far greater number of patients under the conditions of everyday use, or over a long period of time.

When members of the public or health professionals report unlisted side effects with medication via the Yellow Card Scheme, these can be assessed by a team of medicine safety experts at MHRA made up of doctors, pharmacists and scientists who study the benefits and risks of medicines. If a new side effect is found, the MHRA can review the way the medicine is used and the warnings that are given to minimise risk and maximise benefit.

With some medication you may notice a small black triangle alongside the name of the drug. This does not

mean that the medication is unsafe, but that it is being monitored particularly closely. This is always the case if the drug contains a new active substance.

How to report side effects

Anyone in the UK can report an adverse reaction or side effect through the Yellow Card Scheme. You can:

- ask your GP, pharmacist, hospital or NHS drop-in centre
- report online at www.yellowcard.mhra.gov.uk
- call the Yellow Card hotline on 0808 100 3352 (10am-2pm Monday-Friday).

What you will need

You will need the following:

Reporter's details

- this may be you or the person who is reporting the problem on your behalf

Patient's details

- including weight, height and ethnicity

Suspect medicine

- name of epilepsy drug
- start date and dosage
- reason for taking the medication
- action taken as a result of the side effects, for example reduced/increased dosage,
- where you obtained the medication

Suspected side effects

- type of side effect with start and finish date as applicable
- outcome for each side effect
- how side effects affected you
- do you think there was a mistake in prescribing/administering the medication

Additional details

- any other medication taken
- your health professional's details
- permission to contact you to discuss your issues further (optional)
- permission to contact your healthcare professional (optional).

If you have experienced any problems after being prescribed a different version of your usual epilepsy drugs, we would like to know. Please email [Epilepsy Society at policy@epilepsysociety.org.uk](mailto:policy@epilepsysociety.org.uk) or write to us at the address on page 2.

For all news and updates about epilepsy medication, go to www.epilepsysociety.org.uk/epilepsy-medication-updates