The Yellow Card scheme

epilepsy society

Reporting side effects

As with any drug, anti-seizure medication (ASM), can cause side effects in some people. Side effects vary from one ASM to another. Most side effects for an ASM will be listed in the Patient Information Leaflet (PIL), which comes with the ASM. However, some rare, or previously unknown side effects will not be listed.

All serious side effects and adverse drug reactions should be reported, even if the side effect is well known. If you suspect that a side effect may be caused by your medication, you should report it. It doesn't have to be proven. You can do this via the Yellow Card scheme.

What is the MHRA?

The Medicines and Healthcare products Regulatory Agency (MHRA) licenses drugs to be used in the UK. It also monitors the effectiveness and safety (called 'pharmacovigilance') of all medicines once they are licensed and being used.

Part of this includes monitoring the side effects of drugs, and identifying any problems which may not already be known about.

What are side effects?

Side effects are symptoms caused by medical treatment. They are sometimes called 'adverse effects' or 'adverse drug reactions'.

Side effects are often unwanted or unpleasant, but some may be positive (such as causing sleepiness if you find it hard to sleep). You can report side effects via the Yellow Card scheme for any medication that you take.

For the Yellow Card scheme, breakthrough seizures are also considered a 'side effect' of medication.

What else should I report?

Alongside reporting side effects, the Yellow Card scheme can be used to report any effects from switching between different versions of an ASM, such as breakthrough seizures or more frequent seizures.

'Breakthrough seizures' is a term used to describe seizures that happen when someone's epilepsy has otherwise been well controlled. This means people who stop having seizures but then unexpectedly have another seizure.

For some ASMs there are several different versions of the same drug available. This might include a branded drug (the original version of the drug) and other generic versions (with the same active ingredient as the original version). Alternative versions might be different in size, shape, or colour, but they all have the same active ingredient (the chemical part of a drug that works in the body to control or treat a condition or disease).

Although all versions of a drug must have the same amount of active ingredient as the original version, there can be differences in some of the other ingredients (such as colours and binding agents). For some people these changes might affect how well the drug works to control their seizures.

Visit epilepsysociety.org.uk/generic-branded

If you have had your ASM switched from one version to another, and you experience any of the following, you can report this through the Yellow Card scheme:

- a breakthrough seizure;
- seizures different from those you normally have;
- more or worse seizures; or
- worse side effects.

The Yellow Card Scheme is for reporting previously unknown side effects of drugs, and also for reporting 'breakthrough seizures' due to switching between different versions of your medication.

Helpline 01494 601400
Confidential, national call rate.
Information and emotional support.
Visit epilepsysociety.org.uk/helpline for opening hours.

Why should I report this?

The MHRA has issued guidance about whether switching between different versions of ASM can affect seizures. By reporting any changes in your seizures through the Yellow Card scheme, you are helping to show the impact of switching ASM. This will help the MHRA to understand the risks around switching ASM, and inform what future guidance they give to healthcare professionals.

Drug development and side effects

When new drugs are developed, part of the process is 'clinical trials' to test the drug for safety (that it doesn't cause illness), effectiveness (how well it works for the condition it is designed to treat) and whether it causes any common or predictable side effects.

During development, drugs are tested on people. First they are tested on healthy volunteers (without the disease or condition the drug is being developed for) to give information about how the drug distributes in the body, and the likely doses needed.

They are then tested in people with the relevant disease or condition to test their effectiveness on that disease or condition. Some groups of people are not included in these trials: children, people aged 60 or over, and pregnant women, so the effect in these groups is not known at this stage. Once licensed, drugs can be prescribed and used.

Aren't all side effects of a drug already known?
Any side effects that become known when drugs are developed are recorded, and listed in the PIL. These side effects are listed according to how often they happen (how many people are likely to experience the side effect). They are listed as:

- very common – affects at least 1 in 10 people;
- common – affects 1 in 100 to 1 in 10 people;
- occasional – affects 1 in 1,000 to 1 in 100 people;
- rare – affects less than 1 in 1,000 people;
- very rare – affects less than 1 in 10,000 people; and
- extremely rare – affects less than 1 in 100,000 people.

Some side effects only become known after a drug is used in the population (after it is licensed and starts to get prescribed to a larger number of people).

This might be because the side effects only happen after a drug is used for a long time (long-term or 'chronic' side effects), or they become known after a greater number of people have started to use the drug. Also, some side effects are unique to the person experiencing them and so cannot be predicted.

More about the Yellow Card scheme

How do I report side effects or breakthrough seizures?
You can report these on the Yellow Card reporting site online or you can download the Yellow Card app.

If in doubt about what to report, you could ask your doctor or your pharmacist.
Visit yellowcard.mhra.gov.uk

What information will I need to include?
When you report a side effect, you will be asked about:

- what the side effect is;
- the person who had the side effect;
- the medicines which may have caused the side effect;
- your doctor (optional); and
- you – the person making the report.

What happens once I report it?
Doctors, pharmacists, and scientists at the MHRA look into each Yellow Card report. They compare it with other information on the medicine (from the development trials) to check if it is a previously unknown side effect, and consider how it affects the safety of the medicine. They might also be able to issue relevant warnings and safety advice about taking the medicine. Sometimes the MHRA may come back to you to ask for more information.

Epilepsy Society is grateful to Dr F J Rugg-Gunn, Consultant Neurologist & Honorary Associate Professor, Clinical Lead, Chalfont Centre for Epilepsy, who reviewed this information.

For a printed copy of this information contact our helpline.

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