

## Why report suspected side effects?

### Making medicines safer for everyone

All medicines can cause unwanted side effects (sometimes called **adverse drug reactions**) in some people. Many side effects are mild, but some can be serious and even life-threatening. Occasionally, side effects can appear after a person has stopped taking a medicine.

Some side effects are not known about until many people have been taking the medicine for a long time. That's why it is important for people to report suspected side effects.

It is especially useful to know about:

- ◆ a suspected side effect that is not mentioned in the patient information leaflet supplied with the medicine
- ◆ a suspected side effect that causes problems bad enough to interfere with everyday activities
- ◆ a suspected side effect that happens when you're taking more than one medicine, and could be caused by interactions.

Sometimes, it is difficult to tell whether a symptom is a side effect of your medicine, or something else. Even if you're not sure, please make a Yellow Card report if you think a medicine might have caused a side effect.

### What to report

You can report suspected side effects of any medicine or herbal remedy, whether it was prescribed by your doctor or bought without a prescription.

You can report side effects that have happened:

- ◆ to you personally
- ◆ to your child
- ◆ to someone you're responsible for, or someone who asks you to make a report on their behalf.

### How are Yellow Card reports used?

The Medicines and Healthcare products Regulatory Agency (MHRA) collects Yellow Card reports from people taking medicines, as well as from healthcare professionals such as doctors, pharmacists and nurses.

These reports are used to identify side effects and other problems which might not have been known about before. If a new side effect is found, the MHRA will review the way that the medicine can be used, and the warnings that are given to people taking it.

### What is the MHRA?

The MHRA is a UK government body. Its principal aim is to protect the public's health. It does this by making sure that medicines and medical devices work properly and are acceptably safe.

When any possible problem is found, the MHRA takes prompt action to protect the public.

#### For more information about the MHRA:

- ◆ visit [www.mhra.gov.uk](http://www.mhra.gov.uk)
- ◆ or telephone **020 7084 2000**

#### If you are concerned about the safety of a medical device

You can also report this to the MHRA. For information about how to do so:

- ◆ visit [www.mhra.gov.uk](http://www.mhra.gov.uk)
- ◆ or ask your doctor or pharmacist.

## How to report a suspected side effect

### There are three ways to make a Yellow Card report

- ◆ use the online Yellow Card form at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)  
This is the easiest way to make a report, if you have access to the Internet.
- ◆ complete the attached Yellow Card form, and send it back in the envelope provided (there's no need for a stamp)
- ◆ call the Yellow Card hotline on **0808 100 3352**

### Completing the Yellow Card form

If you decide to use the attached form, please complete as much of it as you can, including all the lines marked with \*. You will find it helpful to have your medicines with you when you complete the form.

The form has five sections:

- 1** About the suspected side effect.
- 2** About the person who had the suspected side effect. Give as much information as you can, even if you prefer not to include a name.
- 3** About the medicine(s) which might have caused the side effect. Because side effects can be caused by interactions between medicines, we need to know about all medicines or herbal remedies being taken when the side effect happened.
- 4** About your doctor (*optional*). If you give permission for us to contact your doctor, supply contact details.
- 5** About you – the person making the report. We need a name and contact details, so we can get in touch if we need more information. Give a postal address, even if you prefer not to give a phone number or email address.

**Please sign and date the form before you post it in the attached envelope.**

### If you need more space...

If there is not enough space in any section of the Yellow Card form for you to write as much as you need to, write on a separate sheet of paper and enclose it in the envelope with your form.

### If you need help...

- ◆ call the Yellow Card hotline on **0808 100 3352**
- ◆ or ask a healthcare professional (such as your doctor, nurse or pharmacist) for help.

### What happens next?

The MHRA will send an acknowledgement of your Yellow Card report.

If you have given permission on the form, we will send a copy to your doctor.

### Protecting your personal information

On the form, we ask for your name and contact details. This is so we can get in touch if we need more information from you.

**These personal details are kept safe, secure and confidential. They will never be passed on to anyone outside the MHRA without your express permission.**

If you want to make a report but don't want to tell us your name, you can ask someone else to complete the form for you, giving their contact details.

The MHRA regularly publishes data about information given on Yellow Card reports, but this never includes the names or other personal details of the people who made the reports.

## More information

If you are worried about a symptom you think may be a side effect:

- 1** Check the patient information leaflet supplied with the medicine. This lists the known side effects and advises you what to do.
- 2** Talk to your doctor or pharmacist.
- 3** You can also get information from:
  - ◆ **NHS Direct** in England and Wales on **0845 46 47** (textphone 0845 606 4647)\*
  - ◆ **NHS24** in Scotland on **08454 24 24 24** (textphone 18001 08454 24 24 24)
  - ◆ the Yellow Card website at **[www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)**

*The MHRA cannot provide medical advice in individual cases.*

**Always contact your doctor if you are worried about any symptoms.**

\* Calls using BT lines are charged at BT local rates. Other telephone service providers may charge different rates and will supply information on request.

The Yellow Card form goes here

Postage will  
be paid by  
licensee

No stamp required if posted in Great Britain,  
Channel Islands, N. Ireland or the Isle of Man



**Patient Reporting**  
**Medicines and Healthcare products Regulatory Agency**  
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