

**A side effect to your medicine?  
Report it to the  
Yellow Card Scheme  
using this form**

**Your report is important to  
help the MHRA monitor the  
safe use of medicines and  
protect public health.**

# Why report suspected side effects?

## Making medicines safer for everyone

Your report is important and can make a difference. 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 report suspected side effects that:

- ◆ are not in the patient information leaflet found within the box of the medicine.
- ◆ causes problems bad enough to affect everyday activities.
- ◆ happen when you take more than one medicine.
- ◆ may be caused by interactions with other medicines or food.

Sometimes it is hard to tell whether a symptom is a side effect from taking your medicine, or from something else.

If you are unsure, please complete a Yellow Card report and send it to the MHRA. A form is at the back of this booklet, or you can report online [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or via the free Yellow Card app.

For advice about side effects speak to a healthcare professional such as a doctor, pharmacist or nurse. MHRA cannot provide medical advice.

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## What to report

You can report suspected side effects to any medicines, vaccines, herbal medicines and homeopathic remedies, whether it was prescribed or bought, even if from the internet.

### You can report suspected side effects that have happened:

- ◆ to you personally.
- ◆ to your child.
- ◆ to someone you are responsible or caring for, or someone who asks you to report for them.

**Only a suspicion is needed to report.**

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## How are Yellow Card reports used?

The UK medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), runs the Yellow Card Scheme. It collects reports of side effects from people taking medicines, as well as from healthcare professionals such as doctors, pharmacists and nurses also reporting suspected side effects experienced by a patient.

These reports are used to identify side effects and other safety information about medicines 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.

### Reporting suspected side effects



# How to report a suspected side effect

## There are four main ways you can report:

- ◆ **online** at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- ◆ **complete the attached form**, and send it back in the envelope provided (there's no need for a stamp).
- ◆ **call** the Yellow Card reporting line on **freephone 0800 731 6789 (10am to 2pm Monday-Friday only)**
- ◆ using the free **app** – search 'Yellow Card'.

## 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.** Give as much information as you can. You can also tell us if the harm was because of a mistake in how you took the medicine or how it was given to you – this is called a medication error. For example: wrong drug, dose or route; and why (such as, too much medicine taken because of wrong instructions on the pharmacy label, or I accidentally took too much, or I was given the wrong medicine etc). All reports are kept in confidence.
- 2. About the person who had the suspected side effect.** Give as much information as you can, such as age, sex, height and weight. This helps us differentiate between patients on our database. It also helps us understand if certain patients are more vulnerable to experiencing a side effect.
- 3. About the medicine(s) which might have caused the side effect.** If you have it, provide the batch number (BN) which can be found on the medicines box. Sometimes side effects can also happen because of interactions, so we ask you to tell us about all medicines or herbal remedies being taken.

**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, it also helps us get in touch with you if we need more information.

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

If you need more space, write it on a separate sheet of paper and enclose it in the envelope with your form.

**If you need help reporting:**

- ◆ call the Yellow Card reporting line on **freephone 0800 731 6789 (10am to 2pm Monday-Friday only)**. Remember the MHRA cannot give you individual medical advice.
- ◆ or ask a healthcare professional, such as your doctor, nurse or pharmacist for help.

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## **What happens next?**

The MHRA will send an acknowledgement when your Yellow Card report is received. If you have given permission on the form, we will send a copy to your doctor.

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## Protecting your personal Information

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

Your personal details are kept safe, secure and confidential. They will never be passed on to anyone outside the MHRA without your 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 anonymised 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. Further detail about how we handle the information in your report can be found in our privacy policy on the Yellow Card website at: <https://yellowcard.mhra.gov.uk/privacy-policy/> or search 'privacy'.

Sometimes MHRA may want to use your Yellow Card information to encourage others to report, to opt in, tick the box at the end of the form. For example, to develop more detailed case studies to show the importance of reporting a Yellow Card.

Your personal information will not be shared without further communication with you.

# More information

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

- 1. Always read 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, pharmacist or nurse.**
- 3. You can also get information from:**
  - ◆ **NHS 111** in England and Scotland by phone on **111** (textphone 181001 111).
  - ◆ **NHS Direct Wales/Galw IECHYD Cymru** by phone on **0845 46 47\*** (textphone 0845 606 46 47).
  - ◆ the Yellow Card website at **[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**

The MHRA cannot provide medical advice in individual cases.

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

\*Calls using land lines and mobiles are chargeable. Telephone service providers may charge different rates and will supply information on request.

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## What is the MHRA?

The MHRA is a UK government body. Its 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.gov.uk/mhra](http://www.gov.uk/mhra) or telephone **0203 080 6000**

### You can also report online at the Yellow Card website any suspected safety problems or incidents involving:

- ◆ a medical device adverse incident.
- ◆ defective medicines (those that are not of an acceptable quality).
- ◆ a fake (counterfeit) medicine or medical device.
- ◆ safety concerns for e-cigarettes or their refills (e-liquids).

Help us raise awareness about reporting to the Yellow Card Scheme.

See our animation (<https://www.youtube.com/watch?v=3et5LdYLc8M>), infographics and videos about the Scheme under the downloads section of our reporting website. Feel free to share them on social media to help us promote the Yellow Card Scheme.



Use blue or black ink. Complete all the lines marked with \* and give as much other information as you can

## 1. About the suspected side effect

### \* What were the symptoms of the suspected side effect, and how did it happen?

If there isn't enough space here, attach an extra sheet of paper.

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**How bad was the suspected side effect?** Tick the box that best describes how bad the symptoms were.

- \*  Mild  Unpleasant, but did not affect everyday activities
- Bad enough to affect everyday activities  Bad enough to see doctor
- Bad enough to be admitted to hospital  Caused very serious illness
- Caused death  Other \_\_\_\_\_

**When did the side effect start?** \_\_\_\_\_

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**How is the person feeling now?** Tick the box that best describes whether the person still has symptoms of the suspected side effect.

- \*  Better (no more symptoms)  Getting better  Still has symptoms  More seriously ill  Died  Other

**Can you give any more details?** For example, did the person take or receive any other treatment for the symptoms?  
Did they stop taking the medicine as a result of the side effect?

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**Was there a mistake in how the medicine was given or taken?**

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## 2. About the person who had the suspected side effect

**Who had the suspected side effect?**

- \*  You  Your child  Someone else

**Is the patient pregnant?**

- Yes  No  Unknown  N/A

**Information about the person** Supply as much information as you can, even if you prefer not give a name.

First name or initials \_\_\_\_\_ Family name \_\_\_\_\_  Male  Female

- \* Age \_\_\_\_\_ weight \_\_\_\_\_  kg  stones/pounds Height \_\_\_\_\_  metres  feet/inches

**Any other relevant information?**

For example, does the patient have any medical conditions or allergies? If the patient is pregnant, please provide the estimated due date and as much information as you can about this and any previous pregnancies.

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### 3. About the medicine(s) which might have caused the side effect

\* **Name of the medicine** \_\_\_\_\_  prescription  bought in pharmacy  bought elsewhere

Dosage (for example, one 250mg tablet, twice a day) \_\_\_\_\_

bought on the internet

What was it taken for? \_\_\_\_\_ Batch number (BN) \_\_\_\_\_

Start date \_\_\_\_\_ End date \_\_\_\_\_ Did you stop because of side effects?  Yes  No

Give details of other medicine(s) taken at the same time (which might have caused an interaction). Attach an extra sheet of paper, if needed.

**Name of the medicine** \_\_\_\_\_  prescription  bought in pharmacy  bought elsewhere

Dosage (for example, one 250mg tablet, twice a day) \_\_\_\_\_  bought on the internet

What was it taken for? \_\_\_\_\_

Is this medicine thought to have also caused the side effect? \_\_\_\_\_  Yes  No  Possibly

Start date \_\_\_\_\_ End date \_\_\_\_\_ Did you stop because of side effects?  Yes  No

**Were other medicines or herbal remedies taken in the last 3 months?**  Yes  No

What were these (as well as the above): \_\_\_\_\_

### 4. About your doctor or the person's doctor (optional)

We can send a copy of your Yellow Card report to your doctor if you are reporting about yourself or if the person is your next of kin. Would you like a copy of this report to be sent to your doctor or the person's doctor?

Yes  No If yes, give the doctor's name and address

Doctor's name \_\_\_\_\_

If you want us to send a copy of this report to any other healthcare professional, attach a separate sheet with their contact details.

Address \_\_\_\_\_

**If we need more medical information** (such as test results), do we have your permission to contact your doctor directly for it?

\_\_\_\_\_ Postcode \_\_\_\_\_

Yes  No

### 5. About you - the person making the report

**We need contact details** - please supply a full postal address, even if you prefer not to give a phone number or email address.

\* Title \_\_\_\_\_ First name or initials \_\_\_\_\_ Family name \_\_\_\_\_

\* Address \_\_\_\_\_

\* \_\_\_\_\_ Postcode \_\_\_\_\_

Telephone number \_\_\_\_\_ Email address \_\_\_\_\_

### Please sign and date this form

I agree that the Medicines and Healthcare products Regulatory Agency (MHRA) can contact me to discuss the suspected side effect, and to ask for more information that might help understanding of the case and that all information I provide will be handled in line with the Yellow Card privacy policy.

Sometimes MHRA may want to use your Yellow Card information to encourage others to report, to opt in tick the box

\* Signed \_\_\_\_\_ Date \_\_\_\_\_

See our animation and share it on social media to raise awareness about the Yellow Card Scheme: [www.youtube.com/watch?v=3et5LdYLc8M](http://www.youtube.com/watch?v=3et5LdYLc8M)

Please return this form in the envelope provided to: FREEPOST YELLOW CARD. (No other address details are required)

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**Thank you for your  
contribution to the  
Yellow Card Scheme**





FREEPOST YELLOW CARD

You can report suspected  
side effects:

- ◆ online at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- ◆ using the free app
- ◆ using the form inside this leaflet
- ◆ by calling **freephone 0800 731 6789 (10am to 2pm Monday-Friday only)**
- ◆ using the free app – search Yellow Card