

# Did you know?

# You can report side effects yourself

As a patient, you have the right to report unwanted side effects of medicines directly to the authorities. You can also report a side effect on behalf of someone in your care, such as a child or relative.

*Remember to speak to your doctor or pharmacist if you are worried about any suspected side effects.*

## Why report a side effect?

We are always learning more about medicines.

Although they are tested extensively in clinical trials before they are authorised, not everything can be known about their side effects until they have been used by many people over time.

By reporting side effects, you can help to provide more information about medicines, which will ultimately help to make them safer.

## How do I report a side effect?

If you think a medicine has caused a side effect, please check the package leaflet that comes with the medicine for information on how to report it.

You can usually report side effects by filling in a form online or from your doctor or local pharmacy.

For more details, and to report online, please check the website of your [national authority](#) (use these links to ensure you are reporting to the appropriate website).

## What information should I report?

If possible, you should provide the following information when making your report:

- information on the person who has had the side effect (such as age and sex);
- the description of the side effect;
- the dose and the name of the medicine suspected to have caused the side effect (brand name as well as active ingredient);
- the batch number of the medicine (found on the packaging);
- any other medicines being taken around the same time (including non-prescription medicines, herbal remedies and contraceptives);
- any other health conditions that the person who experienced the side effect may have.



# Frequently asked questions

## How do I know I've experienced a side effect?

A side effect (also called an adverse reaction) is an unwanted symptom or effect caused by a medicine.

You cannot always be certain that what you are experiencing is caused by the medicine, but by reporting suspected side effects you can help the authorities in their investigations, which will lead to safer medicines.

## What happens to my report after I've sent it?

Your report, along with other reports on the medicine, will be reviewed by medicines safety experts to see if there is any new information (known as a 'safety signal'). After evaluating the safety signal and all other relevant data, medicines authorities may issue new warnings or advice on how the medicine should be used, and can even stop its use.

## Can I get help with reporting a side effect?

Yes. Your doctor or pharmacist can help you complete your report, and you can also request that they send the report on your behalf. Patients' organisations in your country may also be able to help.

## The medicine has a black triangle symbol in its package leaflet. What does this mean?

The inverted black triangle symbol '▼' serves as a reminder to report any suspected side effects, either because the medicine is new or because there is a particular need to find out more about its long-term safety. The symbol does not mean that your medicine is unsafe.

## Are my personal data protected?

All personal information related to the reporting of a side effect is processed in accordance with EU data protection legislation. Your report is used solely for the scientific evaluation of the medicine.

## Where can I find information on side effects that have already been reported with the medicine?

You can check the package leaflet that comes with the medicine. You can also check the publicly available European database ([www.adrreports.eu](http://www.adrreports.eu)) or contact your national medicines authority for further information.

If you are worried about any suspected side effects from your medicine, please speak to your doctor or pharmacist for advice. You should contact them immediately if you have a side effect that you think is serious or that is listed as serious in the package leaflet that comes with your medicine.