HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HUMAN MEDICINES

Medicines and side effects

OUR ADVICE ON

Medicines and side effects

Medicines can help us live longer and healthier lives. They can help cure or treat an illness or disease and can also prevent some conditions from developing in the first place.

During the course of our lives, it is likely that we will all need to take medicines. These might include vaccines to prevent illness or prescription medicines such as antibiotics to treat serious infections. Some of us may also take over-the-counter (OTC) medicines to treat minor symptoms like headaches as well as dietary supplements such as vitamins.

Most of us will not experience any problems when using medicines. However, all medicines have some risks and a small number of people may develop side effects (also known as adverse reactions). This leaflet tells you what to do if you think you have had a side effect to a medicine.

We encourage people to report suspected side effects so that we have more information available about the use of medicines. This helps us to monitor their safety.

What is a side effect?

A side effect is when something unwanted or unintended happens after taking a medicine. In many cases, side effects to medicines are mild and you can continue to take the medicine. However, for some people the side effects can sometimes be more serious. They may need a change in their medicines or, in rare cases, some additional medical treatment.

It is important to look at the risks associated with a medicine in the context of the overall benefit of the medicine to your health and the condition being treated. Even where a reaction to a particular medicine is severe, it may still be better to continue the treatment and to manage the unwanted side effects.

Where can I get information on side effects?

The package leaflet that comes with a medicine tells you about that medicine. A section of the leaflet deals with possible side effects. Some of this information may also be printed on the product packaging.

It is really important to read this information. You should also talk to your doctor or pharmacist about the possible side effects of medicines they are recommending for you.

What are the chances of having a side effect?

The package leaflet will tell you about the chances of developing side effects. For example, a very rare side effect will affect fewer than 1 in 10,000 people. A very common side effect might affect more than 1 in 10 people taking the medicine.

How do I know if I have had a side effect to a medicine?

Side effects vary and depend on the medicine and the person. Examples of common side effects include headaches, fever, dizziness, skin rashes, nausea, vomiting, diarrhoea and drowsiness. Some side effects may happen immediately while others may develop over time. However, many side effects to medicines are mild and will go away within a few days as your body adjusts to the medicine.

What should I do if I think I have had a side effect?

If you are worried that you may have had a side effect to a medicine, contact your doctor or pharmacist. They will tell you if you need any medical care. They will also consider if you need to change your treatment or if you need a different treatment. They may report the suspected side effect to us at the Health Products Regulatory Authority (HPRA). You can also report a side effect to us directly.

Who can report a side effect?

- Doctors, pharmacists, dentists, nurses and other healthcare professionals.
- Patients and other members of the public if the side effect happened to:
  - themselves personally;
  - their child;
  - some other person they are responsible for, such as a spouse, a young adult or an elderly person; or
  - someone who has asked that they make a report on their behalf.

How can I report a side effect?

You can report a side effect by:

- contacting your doctor or pharmacist who can notify us at the HPRA;
- using the online report form on www.hpra.ie. You can also print the form and post it to us;
- calling us on (01) 676 4971.

Why should I report a side effect?

We encourage you to report suspected side effects so that we have more information available about the use of medicines. This helps us to monitor their safety.

When we get a report of a suspected side effect, we review all the details including the possible impact of the medicine. If we think that the medicine has played a part, we examine to see if this may be a new safety concern or if similar cases have been reported. We also have access to global safety information which helps us to identify emerging safety issues.

Where a serious safety issue emerges with a medicine, we work to change the way the medicine is used. If there is a risk to public health, we may suspend the use of a medicine.

What can I do to reduce the risk of side effects?

Always follow the advice of your doctor and pharmacist on the recommended storage, dose and length of time you should take a medicine. Make sure you tell your doctor and pharmacist about any other medicines you are taking. Some medicines can react with each other and this could be a health risk.

Additional monitoring

Health authorities across Europe carefully monitor the safety of all medicines. Some medicines are monitored more closely than others. These medicines have a black upside down triangle on their package leaflet together with a short sentence that reads:

▼ This medicinal product is subject to additional monitoring.

The black triangle will help you to quickly identify medicines that are being monitored more closely than others but it does not mean that these medicines are unsafe. There may be less information available about them compared to other medicines because, for example, they are new to the market.

If you think you have had a side effect after taking a medicine that has a black triangle, please report it to your doctor, pharmacist or directly to us. It is important that all safety information about the use of the medicine is quickly reviewed.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

As the regulatory authority, we monitor the safety and quality of medicines available in Ireland. Our aim is to make sure that medicines are as safe as possible and do what they are intended to do.

More information

This is one in a series of information leaflets that you can get from the HPRA and from our website: **www.hpra.ie**.

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Phone: (01) 676 4971
Fax: (01) 676 7836
E-mail: info@hpra.ie

www.hpra.ie

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Approved by NALA