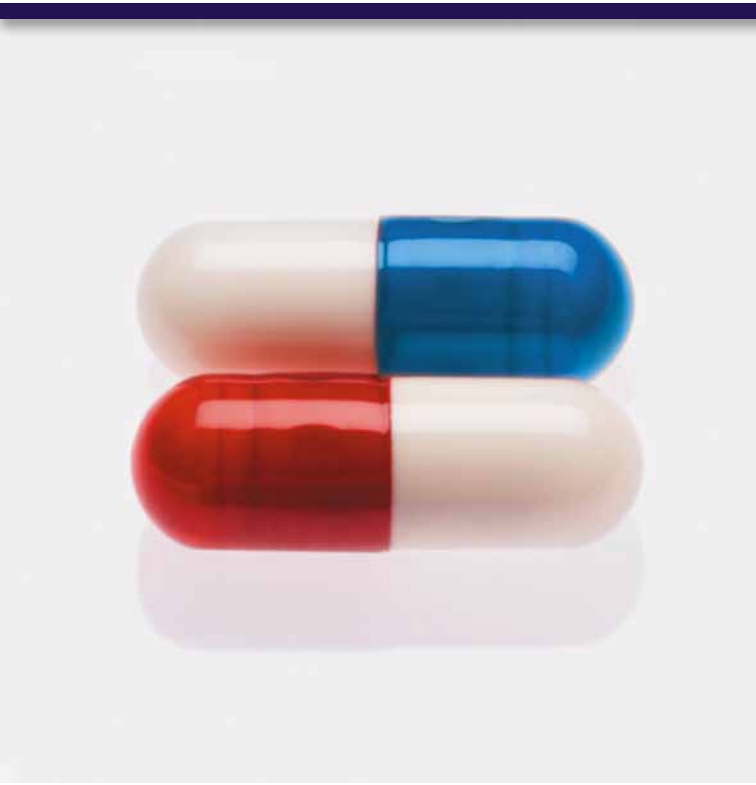
HUMAN MEDICINES

IRISH MEDICINES BOARD

our advice on

generic medicines



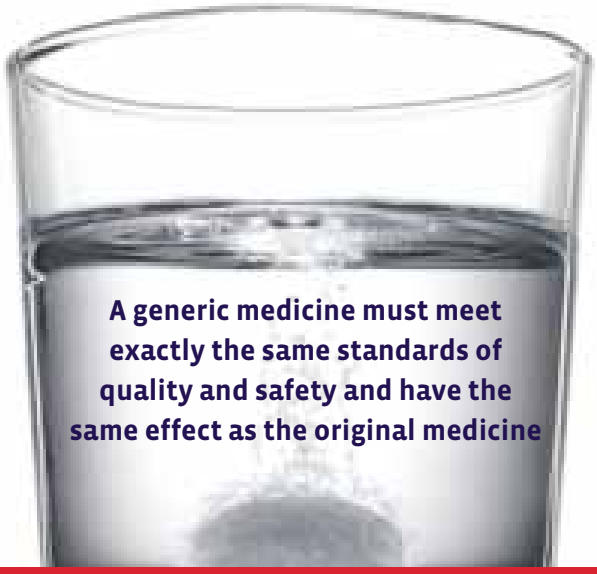
generic medicines

This leaflet answers some of the most common questions about generic medicines. In particular, it includes information about how generics compare to original medicines. You can also discuss the use of generic medicines with your doctor or pharmacist.

What is a generic medicine?

A generic medicine is a medicine that is similar to an original, brand name medicine. It:

- has the same active ingredient as the original medicine, and
- is made to the same standard to make sure it is safe and effective.



A generic medicine treats the same disease or condition as the original medicine

How do generic medicines become available?

When a pharmaceutical company develops a new original medicine, it takes out a patent. The patent is a legal agreement that prevents other companies from making or selling the same medicine for a number of years.

The new medicine usually has a unique name or brand. It can also be called a ‘proprietary’, a ‘reference’ or an ‘originator’ medicine.

When a patent’s time period comes to an end, other pharmaceutical companies can make a similar version – a generic – of the original medicine.

Why are generic medicines used?

Generic medicines can save money for patients and the health service.

Generic medicines usually cost less than the original branded product. This is because manufacturers do not need to invest as much money in research, development and marketing as they would if they were producing an original medicine from scratch.

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How is a generic medicine similar to an original, branded medicine?

- A generic medicine contains the same ingredient (or ingredients) that make a medicine work. This is called the active ingredient. Without this ingredient, the medicine will not provide the same intended treatment or benefit.
- A generic medicine contains the same amount of the active ingredient as the original version, so the required dose of both medicines will also be the same.
- A generic medicine treats the same disease or condition as the original medicine. As the generic version acts in the same way in the body, it is nearly always interchangeable with the original product. In other words, you can usually use either the original or the generic medicine to achieve the same effect or benefit.

If your doctor or pharmacist has prescribed or dispensed a generic medicine, you can be sure it is as safe and effective as the original product

How is a generic medicine different from an original medicine?

- Generic versions of a medicine may have different colours, flavours or combinations of non-active ingredients (for example colourings, starches, sugars) compared to the original product.
- A generic medicine may also be a different shape or size and come in a different box, packet or bottle.

None of these differences, however, affect the way the medicine works.

Generic versions of a medicine may have different colours, flavours or combinations of non-active ingredients compared to the original product

Are generic medicines safe and effective?

Yes. A generic medicine must meet exactly the same standards of quality and safety and have the same effect as the original medicine.

Generic medicines, like original medicines, must go through a number of checks to be sold in Ireland.

They must be authorised by the regulator.

As the national regulator, the Irish Medicines Board (IMB) authorises, or approves, medicines before they can be used in Ireland. The IMB also monitors the safety of medicines available in Ireland once they are in use. If your doctor or pharmacist has prescribed or dispensed a generic medicine, you can be sure it is as safe and effective as the original product.

They must have the same intended effect on the body as the original product.

The result or benefit of using the generic medicine must be the same as the result when using the same dose of the original medicine. A company must complete scientific studies to prove that its generic medicine has the same effect as the original, branded medicine. The IMB reviews the results of these studies before it allows a generic medicine to be sold in Ireland.

generic medicines

They must be monitored for ongoing safety.

As with all medicines, once a generic is in use, it must be monitored in case any side effects are reported. Not only is the drug monitored by the IMB, but, by law, the company that sells it must also continually monitor its safety and report any safety issues to the IMB.

They must be manufactured to a high standard.

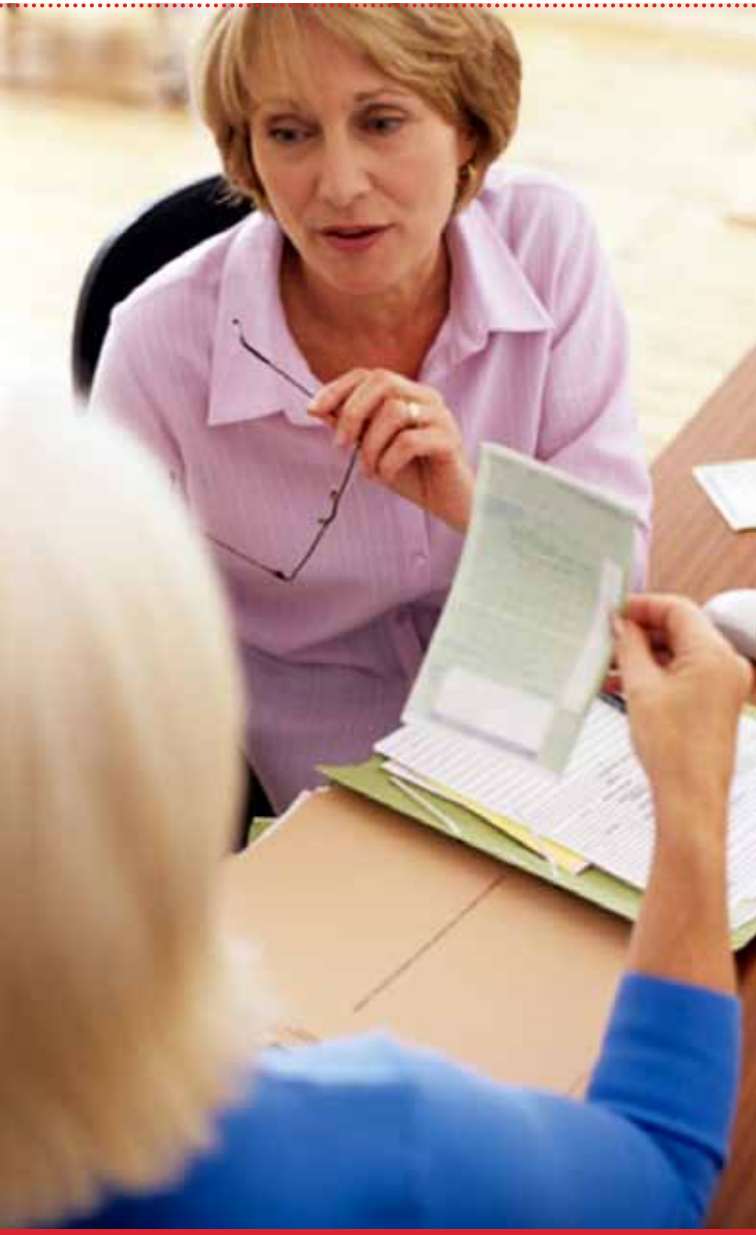
Generic medicines must be manufactured to the same quality standard as all other medicines. To verify this, the IMB will inspect and approve the sites where generic medicines are made.

Does a generic medicine have the same potential side effects as the original medicine?

All medicines have some risks associated with their use. As a generic medicine contains the same active ingredient as the original medicine, it is likely to have the same possible side effects.

The leaflet that comes with the generic medicine will include information about these side effects and outline any differences in non-active ingredients, such as colourings. It is really important that you take the time to read this information.

If you have any questions about the use of generic medicines discuss these with your doctor or pharmacist



Are there any circumstances or situations when I shouldn't use generic medicines?

Yes. For a small number of products, it is not advisable to take different versions of the medicine. This is because your body gets used to the version you are currently taking. Your doctor and pharmacist will tell you if you should not change to a generic version of a medicine you are taking.

Warning: Dangers of buying medicines online

The IMB strongly recommends that you never buy either an original or a generic medicine over the internet. There are no guarantees that medicines bought online are effective, safe or of an acceptable standard of quality, so these products can pose serious health risks to those who use them.

The Irish Medicines Board

The Irish Medicines Board's role is to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products.

What does the IMB do?

As the regulatory authority, the IMB monitors the safety of medicines available in Ireland. We aim to make sure that all medicines on the Irish market are safe, effective and of high quality. We identify and address safety issues so that medicines do not compromise the health of patients.

More Information

This is one in a series of information leaflets that are available from the IMB and from our website www.imb.ie.

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IRISH MEDICINES BOARD

Plain English
Approved by NALA

Irish Medicines Board
Bord Leigheasra na hÉireann

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Phone: (01) 676 4971
Fax: (01) 634 4033
E-mail: imb@imb.ie

www.imb.ie