



## Why do we use generic medicine?

As generic medicines contains the same active ingredient as the innovator medicine, they provide the same therapeutic effect. The generic medicine is meant to be used interchangeably with the innovator medicine, without significant difference in efficacy.

The use of generic medicines is widely practiced not only in Brunei Darussalam but also other developed countries such as Singapore, UK, USA and EU. This is in an effort to contain the escalating healthcare costs and contribute to the long-term sustainability of healthcare. For all these reasons, the World Health Organisation (WHO) has made recommendations to support the use of generic medicines in accordance to respective requirements.

# Generic Medicines



**Contains the same active ingredients as the innovator medicine**



**The manufacturing process of generic medicine has the same standards as the innovator medicine**



**Safe, of quality and efficacious as innovator medicine**

**Department of Pharmaceutical Services  
Ministry of Health  
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# Generic Medicines



***Generic medicines that are registered with Ministry of Health, Brunei Darussalam are of good quality, safe and efficacious***

## What is generic medicine?

Generic medicine contains the same active ingredient as the innovator medicine. An active ingredient is a substance or compound in a medicine that is responsible for the therapeutic effect of that medicine.

Generic medicine can be manufactured by any manufacturer after the patent protection period of the innovator medicine has expired. The manufacturer can then market the generic medicine under a different brand name. For example, Paracetamol is the generic name branded as Panadol.

Generic medicines tend to cost less than their innovator counterparts because generic manufacturers do not have to invest time and money into research and repeat animal and clinical (human) studies that were required of innovator medicines to demonstrate safety and effectiveness. The manufacturing of generic medicines from multiple manufacturers also help keep the cost competitive resulting in a substantially lower price.

## What is innovator medicine?

Innovator medicine is the original brand medicine that is newly created by a pharmaceutical company after extensive research and clinical trials.

The pharmaceutical company that created this innovator medicine is being granted a patent protection period. This means that only the pharmaceutical company that holds the patent is allowed to manufacture and market the medicine. The patent period hence allow them to make a profit from the medicine they develop. After the patent has expired, the medicine can be manufactured and sold by other pharmaceutical companies, usually at a lower price.

## Are generic and innovator medicines same?

Generic medicine is same as innovator medicine in terms of:

- Active ingredient
- Strength of the medicine
- Therapeutic effect
- Safety profile
- Efficacy
- Quality
- Mechanism of action
- Route of administration

## How are generic and innovator medicines different?

They are different in terms of:

- Physical appearance
- Brand name
- Inactive ingredients
- Outer packaging

## How is generic medicine manufactured?

The generic medicine is manufactured under the same strict standards as the innovator medicines and both are required to adhere to the Good Manufacturing Practice guidelines.

## Is the quality, safety and efficacy of generic medicine same as innovator medicine?



Generic medicine contains the same active ingredient, quality, safety and efficacy as innovator medicine.



The manufacturer that produces the generic medicine must conduct a series of comprehensive tests to ensure that the medicine manufactured meets the specified standards. The generic medicine should also demonstrate therapeutic equivalence (or bioequivalence) to the innovator medicine.



The Brunei Darussalam Medicines Control Authority (BDMCA) ensures that all medicines registered in Brunei Darussalam are of good quality, safe and efficacious before they can be marketed. In addition, post - marketing surveillance are in place to ensure that medicines in the market remain safe and effective for the patients and consumers to take.