

## USE OF THE MALTA MEDICINES LIST

The Malta Medicines List supports health care professionals, consumers and patients to find information on the medicines authorised to be placed on the market in Malta.

(Number of medicines with a particular active ingredient authorised to be placed on the market.)

(New search)

Record Id: [REDACTED]

Therapeutic Class:  ANTIINFLAMATORY AND ANTIRHEUMATIC PRODUCTS

ATC Code:  M01AB05

Active Ingredients:  Diclofenac Potassium 50mg

Product Name:  [REDACTED]

Pharmaceutical Form:  FILM-COATED TABLET

Classification:  PoM

Autorisation Number:  [REDACTED]

Licence Number:  [REDACTED]

Licence Holder Name:  [REDACTED]

Licence Holder Address:  [REDACTED]

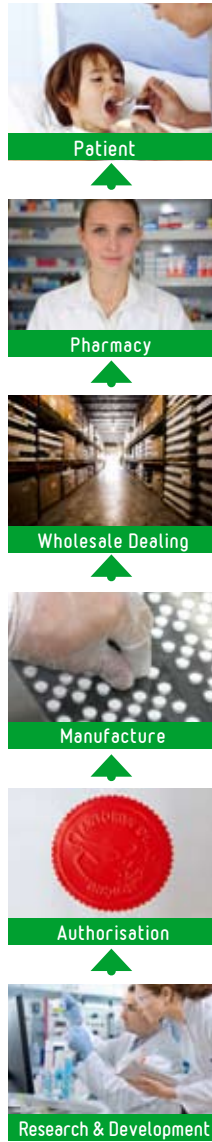
Patient Information Leaflets:  View Documents

(Access the Package Leaflet and the Summary of Product Characteristics.)

**Discuss the choice of your medicines for the same active ingredient (reference medicine or generic medicine) with your doctor and/or pharmacist.**

The Malta Medicines List can be found on: [www.maltamedicineslist.com](http://www.maltamedicineslist.com)

## Distribution Chain



## FALSIFIED MEDICINES

A falsified medicine is one which is deliberately presented in a deceitful way with respect to its content and/or identity and/or source.

Falsified medicines may contain correct or incorrect ingredients, incorrect amount of active ingredient/s, lack of active ingredient/s or with fake packaging. Such falsification can apply to both reference medicines and generic medicines.

Laboratory testing may be required in some cases so as to be able to identify whether a medicine is a falsified medicine or not. Falsified medicines can be very dangerous as they present serious risks to patients' health.

The Medicines Authority regulates the distribution chain (all manufacturers of medicines, importers, wholesale dealers and pharmacies in Malta and Gozo), in order to ensure the quality of the distribution chain, thus protecting the consumers' and patients' health.

Concerns about falsified medicines accentuate when medicines are bought over the internet, since the source may not be regulated and thus may be very difficult to trace.



The information contained in this leaflet is for education and information purposes only.



**MEDICINES**  
CHOICES YOU CAN TRUST

Medicines Authority,  
203, Level 3, Rue D'Argens,  
Gzira.  
[knowyourmedicines.info@gov.mt](mailto:knowyourmedicines.info@gov.mt)  
Helpline (09:00 - 12:00) +356 2343 9111  
[www.knowyourmedicines.gov.mt](http://www.knowyourmedicines.gov.mt)  
[www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)  
[www.maltamedicineslist.com](http://www.maltamedicineslist.com)  
[www.facebook.com/medicinesmalta](http://www.facebook.com/medicinesmalta)

A Maltese version of this leaflet can be accessed on [www.knowyourmedicines.gov.mt](http://www.knowyourmedicines.gov.mt)  
Verżjoni bil-Malti ta' dan il-fujett tinsab f' [www.knowyourmedicines.gov.mt](http://www.knowyourmedicines.gov.mt)

## REFERENCE MEDICINES AND GENERIC MEDICINES



When a pharmaceutical company develops a new medicine, it is granted a legal protection which does not allow other companies to manufacture or sell the same medicine for a number of years. Companies which produce reference (originator) medicines invest in research, clinical studies and development and the legal protection is granted to encourage companies to invest further in these areas, thus providing patients with further means for treatment. Once the legal protection expires, other pharmaceutical companies may produce similar versions - generics - of the reference medicine.

A generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised (the 'reference medicine').

A generic medicine contains the same active ingredient/s as the reference medicine, and it is used at the same dose/s to treat the same condition/s or illness/es as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine.

**All medicines whether reference or generic conform to the established standards of quality, safety and efficacy, and can only be placed on the market in Malta, only after an authorisation is granted.**

## SIMILARITIES AND DIFFERENCES BETWEEN REFERENCE MEDICINES AND GENERIC MEDICINES

|   |                     |   |
|---|---------------------|---|
| <p><b>Active Ingredient/s</b><br/>Ingredient in a medicine which produces an effect on a particular condition or illness. Example: paracetamol.</p>   | Essentially similar | In some cases there can be minor differences between reference medicines and generic medicines, but these are considered to have the same active ingredient, as long as these do not significantly impact on the properties with respect to safety and/or efficacy. |
| <p><b>Pharmaceutical Form</b><br/>The form in which the active ingredient is presented. Example: tablet or syrup.</p>                                 | Same                | Reference medicines and generic medicines can have different shape, colour and unit size and may have different packaging and pack size.  |
| <p><b>Inactive ingredients</b><br/>Ingredients in the medicine other than the active ingredient. Example: flavours, colours, starches and sugars.</p> | May be different    | Inactive substances (excipients) usually do not affect the patient. However, patients may be allergic to certain inactive substances both in reference medicines and generics medicines. Such excipients are listed on the package leaflet.                         |
| <p><b>Standards for manufacturing, authorisation and distribution of medicines</b></p>  | Same                | Regulatory authorities evaluate both reference medicines and generic medicines in accordance to EU legislation. The same standards apply throughout.  |
| <p><b>Name of Medicine</b><br/>The name given to the medicine by the company.</p>   | Different           | Reference medicines and generic medicines have different names. The name can be a unique name (proprietary) or based on the active ingredient and the company name (non-proprietary).   |

## HOW YOU CAN PARTICIPATE IN THE CHOICE OF YOUR MEDICINES



Reference medicines or generic medicines may generally be used to obtain the same effect or benefit. Differences between reference medicines or generic medicines do not have an impact on the effect of the medicine.

Patients can discuss the choice between reference medicines and generic medicines with the doctor and/or pharmacist. If the doctor does not indicate on the prescription a medicinal product of a particular brand by writing 'branded' or '®' on the prescription, the pharmacist can dispense the medicinal product prescribed or an equivalent medicinal product having the same active ingredient/s, dose, pharmaceutical form and dosage frequency, as the medicinal product indicated on the prescription.

Patients can participate in the choice of their medicine by considering information on alternative medicines including pack size, price and the medicines available at the pharmacy.

**Information on different medicines can be found on:**

[www.knowyourmedicines.gov.mt](http://www.knowyourmedicines.gov.mt)  
[www.maltamedicineslist.com](http://www.maltamedicineslist.com)