

Information on Medicinal Products



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Introduction



What is the most important information on medicinal products which industry/ health care professionals/ patients seek/ ask for?

Objectives of the Session



- To better understand what Maltese consumers/patients know about their medicines
- To understand the communication strategy of the Medicines Authority
- To increase awareness on trusted sources on medicines



- Introduction on Information on Medicinal Products
- Medicines Authority Objective
- Core Quality Principles
- Medicines Authority Communication Strategy
- 'Trusted' Communication Sources

Introduction on Information on Medicinal Products

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A definition of information



... stimuli
that has meaning
in some context
for its receiver

Why providing information?



The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.

Directive 2001/83EC, Preamble (40)

Why providing information?



Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.

Directive 2001/83EC, Preamble (52)

- Introduction on Information on Medicinal Products

Medicines Authority Objective

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Objective 5 of the MA



The Medicines Authority has a national public health remit with respect to pharmaceutical activity, information about medicinal products, and the availability and use of medicinal products on the local market.

- Introduction on Information on Medicinal Products
- Medicines Authority Objective

Core Quality Principles

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Core Quality Principles



On 26 June 2007 the Pharmaceutical Forum agreed on a set of core quality principles on information to patients on diseases and treatment options:

- objective and unbiased
- evidence-based
- Reliable
- Accessible
- relevant and appropriate
- patient-oriented
- up to date
- understandable
- transparent
- consistent with statutory information

Objective and Unbiased



Information is objective when it is based on facts and not influenced by prejudices or personal perceptions.

Information is unbiased when it is impartial, non-directive and balanced.

These two definitions do not relate to the source of information which is a separate issue (see the 'Transparent' principle)

Patient-Oriented & Understandable



Information provided should be patient-centred taking into account patients' needs and expectations in order to empower patients.

Patients should be involved in the production and dissemination of information on diseases and treatment options wherever possible.

Information provided should be comprehensible for a patient/citizen.



The evidence base for any information resource needs to be clearly stated, including making clear the level of evidence.

Information should be verifiable, based on comparisons and backed up by scientific peer review where possible.

Information should be kept up-to-date and the date of publication should be included.



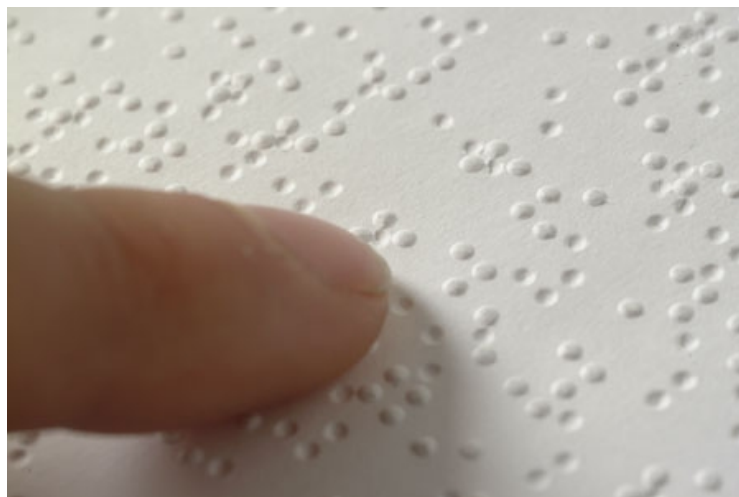
Information needs to be factually correct and not misleading.

Information should be scientifically valid and reflect latest knowledge.



Information should be easily accessible via different mechanisms for example, through written documents, websites of certified official bodies etc.

Information should also be accessible to people with disabilities.





Informed choice requires transparency. That entails transparency of what is known as well as what is not known.

Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular treatment, for example, all need to be made clear.



Information should include issues of relevance and importance to patients' decision-making e.g. including adverse effects.

Impact on quality of life and the consequences of the disease on contribution of the patient to society/the work place are important elements of information on disease.



Information not regulated by statute should, nevertheless, be consistent with the legal requirements of European law (e.g. must not be designed to promote a prescription only medicine, reflecting the prohibition of direct to consumer advertising of prescription only medicines, must not be misleading etc.) and should refer, where appropriate, to statutory information approved through the process of regulation.

- Introduction on Information on Medicinal Products
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- Core Quality Principles

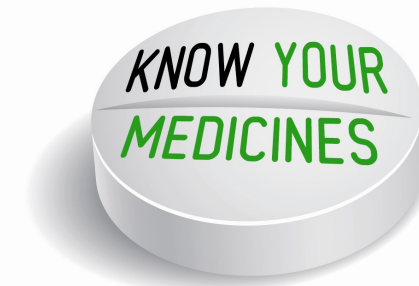
Medicines Authority Communication Strategy

- 'Trusted' Communication Sources

Know Your Medicines



Sustain health care professionals and consumers' awareness, knowledge and trust in the medicines lifecycle and provide information on the regulation of medicines and pharmaceutical activities.



Know Your Medicines



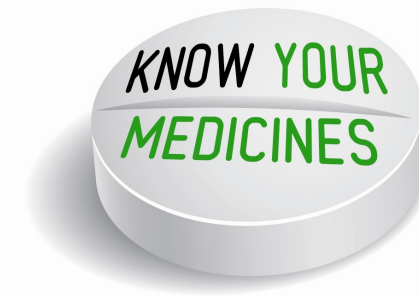
Inform, educate and empower health care professionals and consumers in choice of medicines.



Know Your Medicines



Provide information on medicines and increase awareness of the available resources and promote use of trusted sources (in terms of information).





Research

Malta Medicines List

Micro Site for Consumers

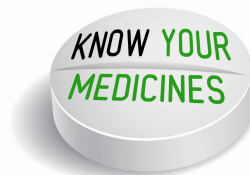
Facebook Page

Information Leaflets/ Posters

Helpline – 23439111

Information Meetings

Participation in Public Events e.g. Science Week



Telephone Interviews



Objectives of the Research

- Identifying participants' general knowledge on medicines
- Identifying participants' awareness in the medicines lifecycle
- Identifying participants' trust in medicines
- And identifying participants' awareness on choice of medicines.

Telephone Interviews



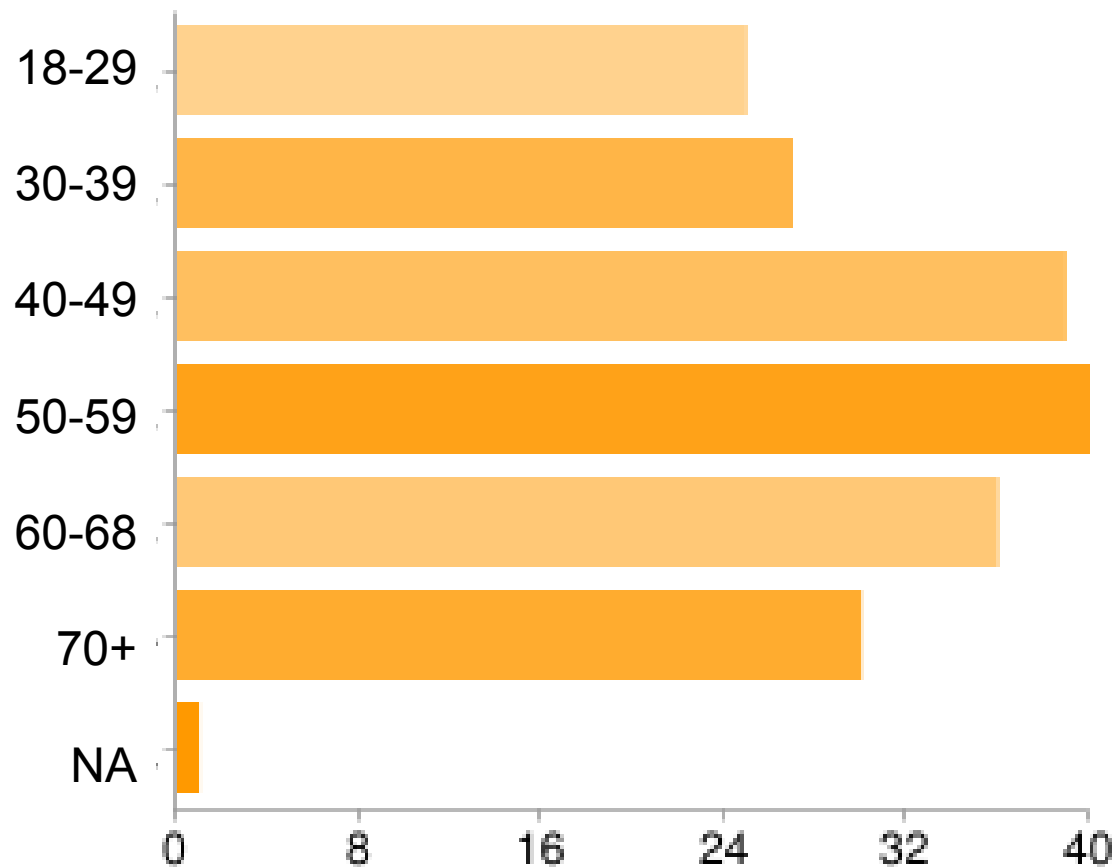
Participation

- 200 Telephone Interviews
- September 2010 – January 2011, 8am -8pm
- 82 Male, 116 Females

Telephone Interviews



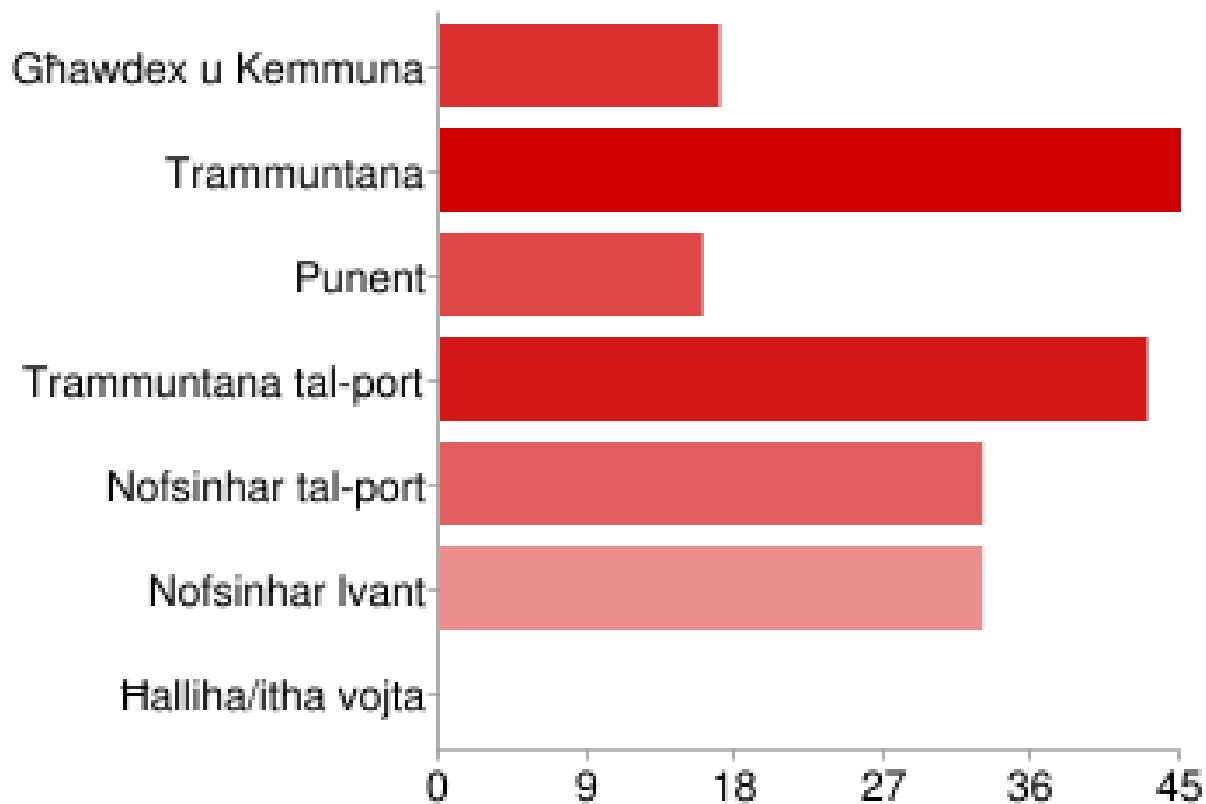
Ages of Participants



Telephone Interviews



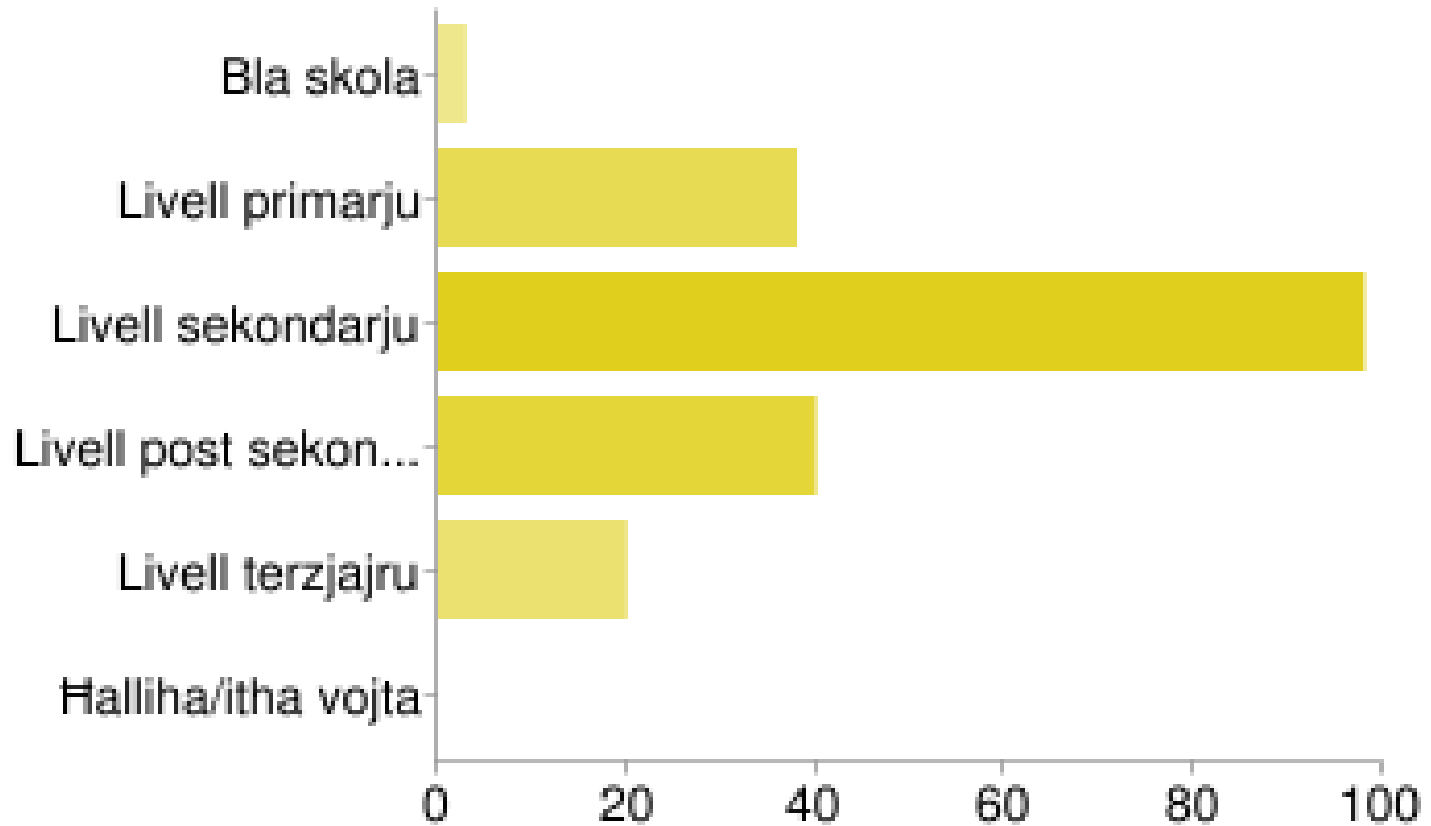
Region



Telephone Interviews



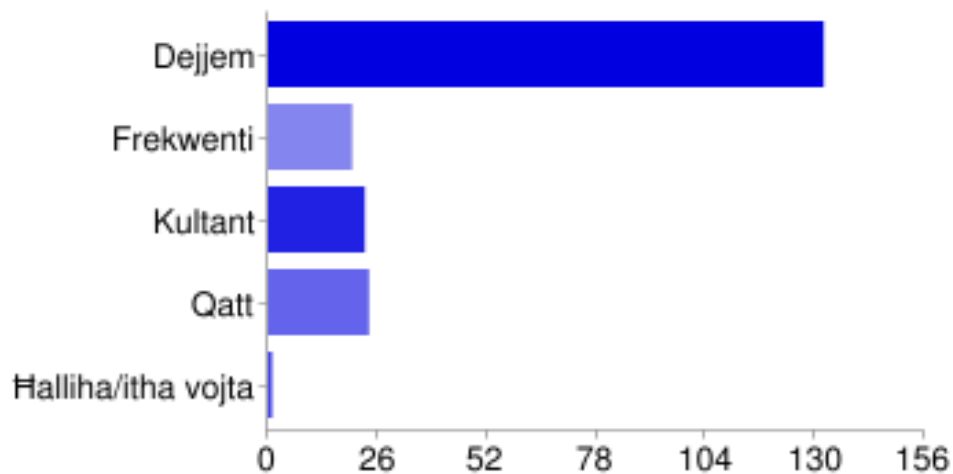
Eduaction Level



Telephone Interviews



Do you seek advice or information before taking a new medicine which does not require a prescription?



<i>Always</i>	66%
<i>Frequently</i>	10%
<i>Sometimes</i>	12%
<i>Never</i>	12%

People may select more than one checkbox, so percentages may add up to more than 100%.

Telephone Interviews



If yes, from the following list, where do you typically seek advice on medicines which do not require a prescription?

Doctor	58%
Pharmacists	29%
Other HCP	2%
Family/ Friends	1%
Television/ Radio	2%
Internet	6%
Books/ Magazines	1%
Other	1%

People could select more than one checkbox

Telephone Interviews



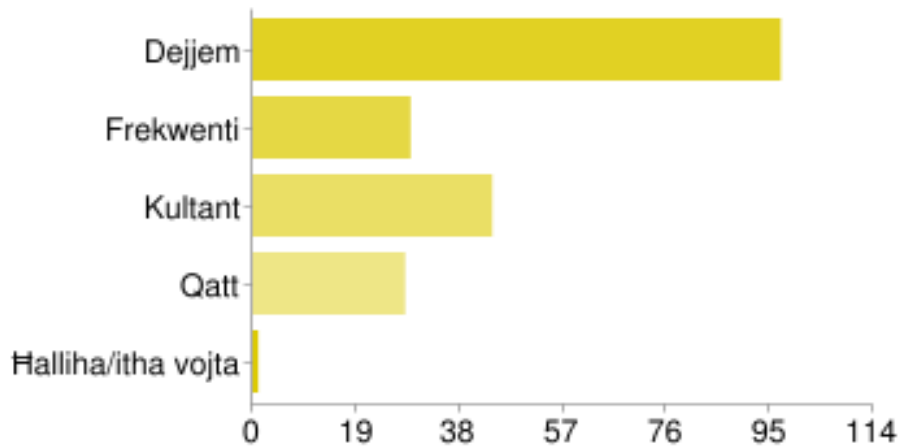
Which source of information on medicines would you trust most?

Doctor	91%
Pharmacists	5%
Other HCP	1%
Family/ Friends	0%
Television/ Radio	0%
Internet	0%
Books/ Magazines	0%
Other	1%
Don't trust any of the above	1%

Telephone Interviews



Do you read medicines' product information leaflet before taking an OTC medicine for the first time?



Always	49%
Frequently	14%
Sometimes	22%
Never	14%

Telephone Interviews



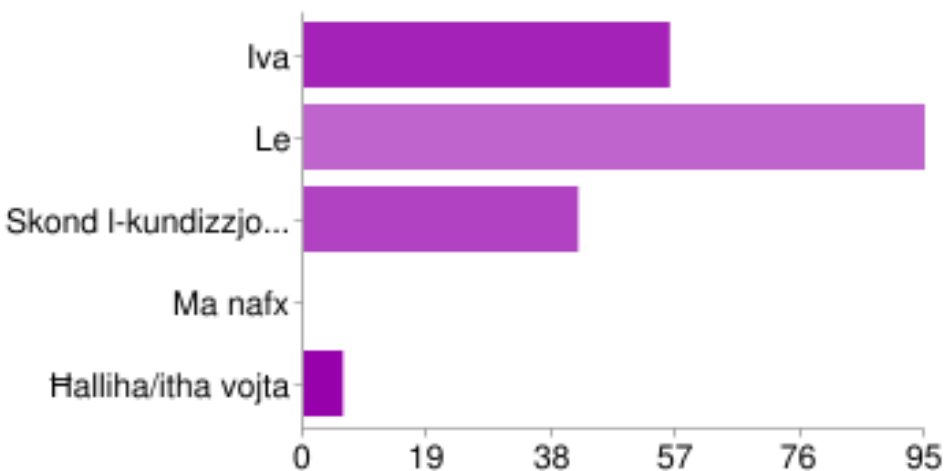
If not, why?

<i>My Doctor gives me necessary information</i>	41%
<i>Pharmacist gives me necessary information</i>	16%
<i>Other health care professionals give me necessary information</i>	1%
<i>Family and friends give me necessary information</i>	5%
<i>Television / Radio give me necessary information</i>	1%
<i>Internet gives me necessary information</i>	5%
<i>Books / Magazines give me necessary information</i>	1%
<i>Can't be bothered</i>	8%
<i>No reply (?)</i>	16%
<i>Other</i>	6%

Telephone Interviews



If a prescribed medicine works for you, do you recommend it to your neighbour / friend / relative with a similar sickness / condition?



Yes	28%
No	48%
Depending the condition	21%
Don't Know	0%
No reply	3%

Telephone Interviews



Do you know the difference between Originator and Generic Medicine

Yes	12.5%
No	85.5%
Don't Know	3%

Telephone Interviews



Using the internet

71% of those who use the internet find it as a very good or good source of information on medicines.

41% of respondents who use the internet say that the internet affects which treatment/ medicine is bought.

3% of respondents bought medicines over the internet due to wider selection, convenience and price.

8% are not concerned about the authenticity or safety of medicines available for sale on the internet

Telephone Interviews



Medicines and house holds

75% of respondents store medicines in humid places such as bathroom and kitchen.

60% of respondents keep medicine until expiry date.

93% of respondents dispose of medicines through normal waste or through sewage system.



Medicines Authority

Awtorità dwar il-Mediċini

Licensing

Post-Licensing

Inspectorate

Regulatory Affairs

Corporate

Health Info



▶ Know more about Medicines Regulation

- [Medicines Regulation](#)
- [Herbal Medicines](#)

▶ Know more about Safety of Medicines

- [Safety](#)
- [Adverse Reactions \(ADRs\) of Medicines](#)

▶ Know more about the Medicines Supply Chain

- [Medicines Supply Chain](#)
- [Over the Counter and Prescription only Medicines](#)
- [Counterfeit Medicines](#)
- [Buying Medicines over the Internet](#)

[News and Events](#)

[Question and Answer \(English\) on Medicines](#)

[Question and Answer \(Maltese\) on Medicines](#)

X'TAF FUQ IL-MEDIĊINI TIEGHEK?



INFORMA RUHEK

- ✔ Staqsi lit-tàbib u lill-ispizjor fuq il-mediċini tieghek
- ✔ Aqra l-fuljett ta' taghrif li ssib mal-mediċina tieghek
- ✔ Staqsi hawn għal-materjal bl-informazzjoni fuq il-mediċini

www.knowyourmedicines.gov.mt
knowyourmedicines.info@gov.mt
 Helpline (09-00 - 12-00) +356 2343 9111



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'Trusted' Information Sources



Malta Medicines List

The Malta Medicines List helps Health Care Professionals and Consumers to find information about which medicinal products are authorised to be placed on the local market.

The screenshot displays a web interface for the Malta Medicines List. At the top, there is a navigation bar with a search box containing '1 of 12824', a 'Display Record:' dropdown set to '1', and an 'Export' button. Below this, the details for 'Record Id: 1' are listed in a table-like format with expandable fields:

Therapeutic Class:	VITAMINS
ATC Code:	A11CC03
Active Ingredients:	Alfacalcidol 1mcg
Product Name:	One-Alpha
Pharmaceutical Form:	CAPSULE
Classification:	PoM
Authorisation Number:	AA244/17701
Licence Number:	PL0043/0050
Licence Holder Name:	P & D Pharmaceuticals Limited
Licence Holder Address:	38, Woolmer Way, Bordon Hampshire GU35 9QF, United Kingdom
Patient Information Leaflets:	View Documents

A small warning icon and text at the bottom right of the record details state: 'Please note that not all searches retrieve the product'.

'Trusted' Information Sources



Malta Medicines List

1 of 4 | Display Record: 1 | Export

Record Id: 9633

Therapeutic Class:	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
ATC Code:	M01AB05
Active Ingredients:	Diclofenac Potassium 50mg
Product Name:	Areston
Pharmaceutical Form:	FILM-COATED TABLET
Classification:	PoM
Authorisation Number:	MA032/00801
Licence Number:	NOT APPLICABLE
Licence Holder Name:	Medochemie Limited
Licence Holder Address:	1-10, Constantinoupleos Street, 3011 Limassol, Cyprus
Patient Information Leaflets:	View Documents

← ATC Code and Therapeutic Class

'Trusted' Information Sources



Anatomical Therapeutic Chemical (ATC) Classification System

It is controlled by the World Health Organisation (WHO) Collaborating Centre for Drug Statistics Methodology (WHOC), and was first published in 1976. The classification system divides medicines into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics.

In this system, medicines are classified into groups according to the active substance and its indications. Further information may be found on the WHO ATC website: http://www.whocc.no/atc_ddd_index/

'Trusted' Information Sources



Active Ingredient, Product Name and Pharmaceutical Form

1 of 4 | Display Record: 1 | Export

Record Id: 9633

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Patient Information Leaflets: View Documents

← Active Ingredient

← Product Name

← Pharmaceutical Form

'Trusted' Information Sources



Active Ingredient and Product Name

Active Ingredient - Some medicinal products may contain more than one active ingredient. An active ingredient is the substance in a medicinal product that is biologically active i.e. produces the desired effect. It is also referred to as active pharmaceutical ingredient (API) or active substance.

Product Name - The authorised name of a medicinal product.



'Trusted' Information Sources



Malta Medicines List

Export All/ Selection

1 of 4 | Display Record: 1 | Export

Record Id: 9633

Therapeutic Class: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ATC Code: M01AB05

Active Ingredients: Diclofenac Potassium 50mg

Product Name: Areston

Pharmaceutical Form: FILM-COATED TABLET

Classification: PoM ← POM or OTC

Authorisation Number: MA032/00801 ← MA, PI, AA

Licence Number: NOT APPLICABLE

Licence Holder Name: Medochemie Limited ← Marketing Authorisation Holder

Licence Holder Address: 1-10, Constantinoupleos Street, 3011 Limassol, Cyprus

Patient Information Leaflets: View Documents

↑ Access to package leaflet and summary of product characteristics

'Trusted' Information Sources



EudrPharm

EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA). EudraPharm has been established to fulfil Articles 57(1)(I) and 57(2) of Regulation (EC) No 726/2004.



Thank You



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