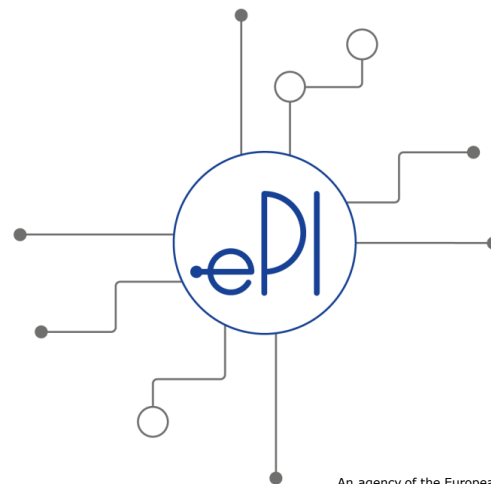




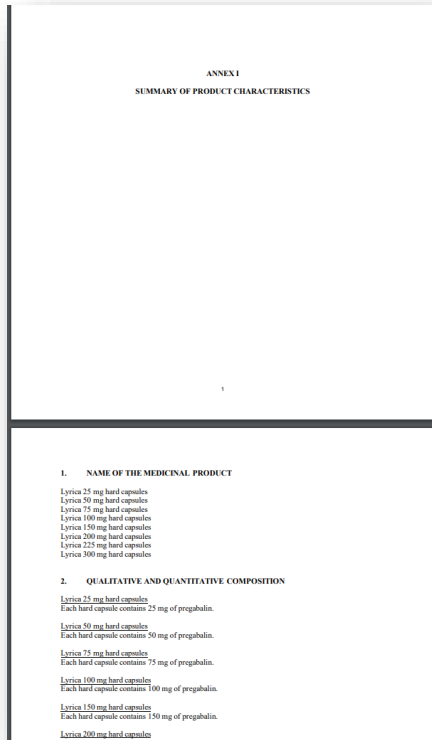
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Electronic Product Information (ePI) for EU medicines



Towards electronic solutions for product information



agencia española de medicamentos y productos sanitarios **cima**

PROSPECTO LYRICA 25 MG CAPSULAS DURAS

Introducción

1. Qué es Lyrica y para qué se utiliza
2. Qué necesita saber antes de empezar a tomar Lyrica
3. Cómo tomar Lyrica
4. Posibles efectos adversos
5. Conservación de Lyrica
6. Contenido del envase e información adicional

Introducción

Gebrauchsinformation: Information für Anwender

Lyrica® 20 mg / ml Lösung zum Einnehmen
Pregabalin

Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Einnahme dieses Arzneimittels beginnen, denn sie enthält wichtige Informationen.

- Heben Sie die Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Wenn Sie weitere Fragen haben, wenden Sie sich an Ihren Arzt oder Apotheker.
- Dieses Arzneimittel wurde Ihnen persönlich verschrieben. Geben Sie es nicht an Dritte weiter. Es kann anderen Menschen schaden, auch wenn diese die gleichen Beschwerden haben wie Sie.
- Wenn Sie Nebenwirkungen bemerken, wenden Sie sich an Ihren Arzt oder Apotheker. Dies gilt auch für Nebenwirkungen, die nicht in dieser Packungsbeilage angegeben sind. Siehe Abschnitt 4.

Was in dieser Packungsbeilage steht

1. Was ist Lyrica und wofür wird es angewendet?
2. Was sollten Sie vor der Einnahme von Lyrica beachten?
3. Wie ist Lyrica einzunehmen?
4. Welche Nebenwirkungen sind möglich?
5. Wie ist Lyrica aufzubewahren?
6. Inhalt der Packung und weitere Informationen

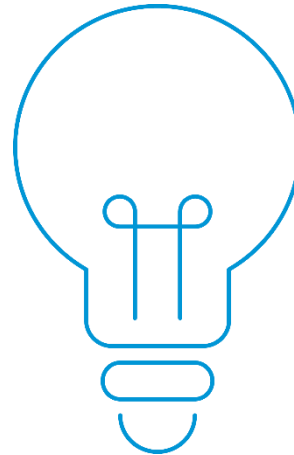
Was ist Lyrica und wofür wird es angewendet?

ca gehört zu einer Gruppe von Arzneimitteln, die bei Erwachsenen zur Behandlung von muskelschwächen, bei Epilepsie und bei bestimmten Angststörungen eingesetzt wird.

Lea todo el prospecto defendid

ePI Key Principles

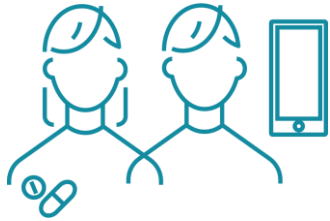
ePI is authorised, statutory product information for human medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using a **common EU electronic standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.



Key principles: adopted by HMA and EMA, published January 2020



ePI facilitates dissemination to patients and healthcare professionals



Access ePI on phone/tablet for all users incl. users with print impairments



Seek reminder of how to take medicine



Go to 'How to take your medicine'
Option to watch video
Or use screen reader



Support rapid roll out of COVID-19 vaccines and therapeutics



Use QR code to link to national language PL



Delivery of vaccine to all EU countries

ePI achievements in 2021

#1

Created an **EU ePI Common Standard** based on FHIR to support harmonisation across the EU and collaboration across the network

#2

Demonstrated a **proof-of-concept prototype** using the EU ePI Common Standard by generating example FHIR-based documents associated with product data to publish on a website.

#3

Developed a realistic medium-term **vision and road map** towards achieving the benefits for stakeholders, HMA, EC, EMA as outlined in the Key Principles for ePI in the EU

ePI deliverable #1 EU ePI Common Standard

EU ePI common standard based on FHIR for electronic product information (ePI) in the EU to support a harmonised ePI across the EU to support collaboration across the network

Fast

Healthcare

Interoperability

Resources

FHIR is: a set of XML (and/or JSON) health data resources, plus a REST API for accessing them



Adopted EU Common Standard for ePI published on GitHub: <https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard> Consisting of:

1. ePI **API Specification** (PDF) and the associated ePI API service list (Excel);
2. A **FHIR XML template** based on the Quality Review of Documents (QRD) template for human medicines;
3. An **instance** of an ePI sample message provided in XML and HTML, along with a sample XSL transformation.

ePI deliverable #2 Proof-of-concept

Prototype was demonstrated

at 5 July Information Workshop

(https://youtu.be/s0_md3zQpJE around 53 min)

- ePI based on the draft EU common standard is:
 - Multilingual
 - Accessible
 - User-friendly
 - Interoperable with SPOR master data providing benefits of structured data

The screenshot shows the ePI interface for the product ELOCTA. The interface is multilingual, with the current language set to English (en). The main content area displays the product information, including a table of contents and detailed text about the product. The text is partially obscured by a large watermark reading "Not for use as medicines information".

ePI deliverable #3 Roadmap

- EU ePI Common Standard developed;
- Public consultation;
- EU ePI Common Standard adopted.

2021

- Creation tool for ePI based on adopted EU ePI Common Standard developed;
- Guidance material created for new products and legacy data.

2022

- Pilot begins;
- Results of pilot feed back to tooling and guidance.

2023-2024

- CAP implementation;
- Phased implementation NAPs;
- EU ePI Common Standard evolves;
- Controlled up-versioning.

Future

Any questions?

Further information

Elizabeth.Scanlan@ema.europa.eu

See websites for contact details

European Medicines Agency www.ema.europa.eu

Heads of Medicines Agencies www.hma.eu

European Commission www.ec.europa.eu

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