

# ekt.one — Electronic Package Insert Management Platform

Accessed via Web / QR Code · Licence#: EKT-2026-01 / e-PI Service Rev. 1.1

⚠ TITCK e-PI Mandatory: 1 January 2027

TITCK IRD-KLVZ-07 Rev.17 Compliant

GDPR / KVKK Compliant

WCAG 2.1 AA

## COMPOSITION

**Active ingredients:** QR-Based Access, Version Control

**Excipients:** Multi-Language Support, Audio Instructions (AI / Studio), Usage Analytics, TITCK Deadline Tracking

**Technical components:** Digital Prospectus · Language Content · Version History · Service Packages · Customer Subscriptions · Usage Analytics · Message Tracking · Activity Management · Scheduled Tasks · QR Code Library

### Scan the code for informational media.

Keep this package insert. You may need to read it again. For further questions contact your system administrator or [support@ekt.one](mailto:support@ekt.one).

### Read this package insert carefully before using ekt.one.

This platform has been prescribed specifically for you; do not transfer it to others. Do not exceed the prescribed subscription package. Attempting to create more prospectuses than your package allows will result in a ValidationError.

## WHAT IS IN THIS PACKAGE INSERT?

- [1.What is ekt.one and what is it used for?](#)
- [2.What you need to know before using ekt.one](#)
- [3.How to use ekt.one](#)
- [4.Possible side effects](#)
- [5.How to store ekt.one](#)

## What is ekt.one and what is it used for?

**ekt.one** is a TITCK-compliant Electronic Package Insert (e-PI) management platform. It enables pharmaceutical companies to provide patients with up-to-date, accessible, and legally compliant digital package inserts via QR codes on drug packaging.

### Mechanism of action

By digitising package insert distribution, eliminating the need for printed inserts

By maintaining TITCK-approved content under version control, archiving every update with date and approver information

By generating a unique QR code for each drug and publishing it at [https://ekt.one/q/<unique\\_code>](https://ekt.one/q/<unique_code>)

### Indications

I-01

### **TITCK e-PI Compliance**

Meeting the mandatory obligation effective 1 January 2027 (TRANSITIONAL ARTICLE 3).

I-02

### **30-Day Update Management**

Reflecting TITCK text changes in the digital environment within the legal timeframe.

I-03

### **Multi-Product Portfolio Management**

Content, version and QR management for 10 to unlimited products from a single panel.

### **QR-Based Access (active ingredient)**

A patient who scans the QR code on the packaging reaches the current package insert within seconds. When each prospectus record is created, the system automatically assigns a UUID (unique\_code) and generates a public URL as [https://ekt.one/q/<unique\\_code>](https://ekt.one/q/<unique_code>). An in-process TTL cache (300 seconds, max. 2000 entries) is active against high concurrent QR scans.

### **Version Control (active ingredient)**

With every **Certify & Publish** action, all language content, audio files and PDF attachments are automatically saved as a snapshot in the version history. Full traceability for TITCK audits is instantly available.

### **Multi-Language Support (excipient)**

Content in Turkish, English, Arabic and any other active language in the system. All language records defined in the system are automatically offered as language options. No extra action is required for foreign-national patients.

### **Audio Instructions (excipient)**

Full access for visually impaired patients via AI or studio voice-over. Audio files in MP3/WAV format can be uploaded per language. Compliant with WCAG 2.1 AA accessibility standard.

## **What you need to know before using ekt.one**

### **Contraindications — Do not use ekt.one**

**ekt.one will not function if the following system requirements are not met:**

- Platform infrastructure is not installed
- PostgreSQL 15 or higher is not installed
- Python 3.11 or higher is not installed
- The qrcode library (pip install qrcode) is not installed
- /mnt/addons-custom is not defined in addons\_path

### **Contraindications — Workflow**

**ekt.one will not allow prospectus creation in the following situations:**

**Relying only on printed inserts:** Packaging with only printed package inserts after 1 January 2027 violates TITCK regulations.

**Using a static PDF link:** An image-only (JPG/PNG) or non-updatable static file link does not meet TITCK standards.

**Creating a prospectus without an active subscription:** The system returns "*No active subscription found*".

**Exceeding package quota:** The system returns "*Package limit reached*".

## Warnings — Use with care

**Inform your system administrator in the following situations:**

If you know the date TITCK made changes to the text — update the **TITCK Approval/Change Date** field; otherwise the 30-day legal deadline tracking cannot be performed.

If you try to publish without marking the content certification ( `content_certified` ) — the system will block the action.

If the product may be exempt from the e-PI requirement — fill in the **e-PI Exemption** field and reason.

## Tests and checks (daily cron tasks)

TITCK Deadline Check	Creates an activity for the responsible user 5 days before deadline; sends a chatter warning if deadline is passed.
Expired Prospectus	Automatically sets prospectuses past their expiry date to <i>Expired</i> .
Expired Subscription	Automatically sets subscriptions past their end date to <i>Inactive</i> .

## Data privacy

### Zero-tracking policy

When a QR code is scanned, no location, contact list or personal data is collected. IP addresses are stored as one-way SHA-256 hashes. No personal data is retained.

## Driving and operating machinery

During peak QR scanning traffic (500+ concurrent reads), the platform maintains its response time thanks to the built-in TTL cache. Drivers are advised to let a passenger handle scanning while holding the drug box.

## Use with other modules (dependencies)

base	Core platform model
website	Public URL and web templates
mail	Chatter, activities, email templates

## How to use ekt.one

Always use ekt.one exactly as described in this package insert. If you are unsure, ask your system administrator.

### Getting started (single dose)

#### Step 01 — Company registration and subscription

Your company registers on the platform. Select the S / M / L / E package according to your product count. Go to **ekt.one** → **Subscriptions** → **New**, select the customer, package type and date range. The system automatically activates the subscription upon saving.

#### Step 02 — Content upload and responsible manager approval

The TITCK-approved PI is uploaded as HTML or PDF. A separate row is created for each language under the **Language Content** tab. The Responsible Manager ticks the Content Certification checkbox and clicks **Certify & Publish**.

#### Step 03 — QR code generation and packaging integration

A unique QR code is automatically generated for each drug. The TITCK mandatory text (*Scan the code for informational media.*) is added automatically. The QR code can be printed from the PDF report.

#### Step 04 — Patient access and analytics

When the QR is scanned, the patient accesses the current insert. Access data (views, downloads, audio plays, language changes) is logged in a GDPR/KVKK-compliant manner.

### Approval workflow (recommended treatment regimen)

**Draft**

→

**Review**

→

**Approved**

→

**Certified**

→

**Published**

→

**Version ++**

1. Create Draft	New Prospectus form	Active subscription + quota
2. Submit for Review	<i>Submit for Review</i>	Product and company selected
3. Approve	<i>Approve</i>	e-PI Manager role

4. Content Certification	<i>Content Certification</i> checkbox	Content must match TITCK text
5. Certify & Publish	<i>Certify &amp; Publish</i>	content_certified = True
6. Automatic Snapshot	— (system does this)	All language content archived

### Package selection (posology)

<b>S</b>	Up to 10	X	X	X	X	X
<b>M</b>	Up to 50	✓	X	✓	X	X
<b>L</b>	Up to 100	✓	✓	✓	✓	X
<b>E</b>	Unlimited	✓	✓	✓	✓	✓

### TITCK update tracking

Enter the date TITCK updated the text in the **TITCK Approval/Change Date** field. The system automatically:

Calculates **Update Deadline** = TITCK Date + 30 days

Creates an *Activity* for the responsible user 5 days before the deadline

Sends a chatter warning if deadline is passed and the prospectus is still published

#### If update is delayed

Prospectuses with an overdue TITCK update deadline are flagged as update\_overdue = True. This carries a risk of non-compliance with TITCK regulations.

### Special use cases

**e-PI Exemption** Check the *e-PI Exemption* box and select the reason (Small Package, Radiopharmaceutical, etc.). Quota control does not apply to exempt products.

**Products with expiry dates** Fill in the *Expiry Date* field. The cron task automatically sets the prospectus to *Expired* once the date passes.

**Analytics tracking** Access view, download, audio play and language change data from *ekt.one* → *Analytics*.

#### Forgotten step — certification checkbox not ticked

When Certify & Publish is clicked, the system returns "You must approve the content certification before publishing." The action is blocked. Tick the content\_certified checkbox first, then try again.

#### Stopping treatment — cancelling a prospectus

Prospectuses no longer in use can be set to cancelled via the *Cancel* button. This removes them from the quota calculation.

## Possible side effects

Like all platforms, `ekt.one` may cause side effects, although not all of these will occur in every user.

**If any side effect becomes serious, contact our support team.**

`support@ekt.one` · Your feedback helps improve the platform.

### Very common — occurs in more than 1 in 10 users

**Paper savings:** elimination of printed insert costs

**Package quota exceeded error:** Upgrade your subscription package or cancel an existing prospectus.

**No active subscription found error:** First create a subscription for the company.

### Common — occurs in 1 in 10 users

**Responsible manager relief:** TITCK deadline alerts arrive automatically

**Confidence in content currency:** version history always accessible

**Content certification missing warning:** Tick the `content_certified` checkbox.

**TITCK update deadline activity:** Update the content within 30 days.

### Uncommon — occurs in 1 in 100 users

**Reduction in patient dissatisfaction:** instant access, audio reading, multi-language

**Unexpected version number increment:** Every *Certify & Publish* action increments the version — this is a feature, not a bug.

### Rare — occurs in 1 in 1000 users

**Elimination of TITCK audit anxiety:** full audit trail, all versions in archive

**QR cache delay (max. 300 seconds):** Update reflects automatically when in-process TTL cache expires. Redis cache support is recommended for high-traffic environments.

## How to store `ekt.one`

Keep out of the reach and sight of children and store in a production environment.

Operate in server conditions of 15–25°C, 40–60% humidity.

Never commit the `.env` file to a git repository.

Back up the PostgreSQL database at regular intervals.

Check the module version: 19.0.1.0.0 — obtain a new prescription when upgrading to a new platform version.

Set unused/cancelled prospectuses to *cancelled* or *expired* status to free up storage.

### Compliance commitments

- ✓ **TITCK IRD-KLVZ-07 (Rev. 17, 18 March 2026)** — 30-day update deadline tracked automatically.
- ✓ **KVKK / GDPR — Zero-tracking policy** — IP addresses stored as SHA-256 hashes.
- ✓ **WCAG 2.1 Level AA** — Screen reader, audio instructions, keyboard navigation.
- ✓ **99.9% Uptime SLA** — The QR code on the drug box works everywhere, at all times.

Do not use expired or uninstalled module versions. Compatibility with different platform versions is not guaranteed.

### Marketing Authorisation Holder

Kardan.Digital Software Inc.

Web: [ekt.one](https://ekt.one) · [kardan.digital](https://kardan.digital)

E-mail: [support@ekt.one](mailto:support@ekt.one)

Licence: LGPL-3

### Technical requirements

ekt.one Platform v19

Python 3.11+ · PostgreSQL 15+

Module: 19.0.1.0.0

Dependency: `pip install qrcode`

This package insert was approved in **March 2026**.

*This package insert has been prepared for promotional and demo purposes only. It does not belong to any medicinal product registered with TITCK.  
ekt.one is a software platform.*