Perusrekisteri
Basic register for medicinal products produced by Fimea

Versiotiedot
Itemise the deliverable batch

Ajopvm
Run date of the material (e.g. 23-01-2021)

Aineistoera
Material batch identification data. Year and current date.

Kkera [0..1]
Material batch specifier. First or second half of month.

Kattavuus
Which part of the register is included in this run. Always 1.

Pakkaus [0..*]
Concrete distribution form of medicinal product. Can include several pharmaceutical products.

Laakevalmiste-ref
Package-Medicinal product -relation, only one “Laakevalmiste” is connected to each package.

Pakkaustunnus
Invariable technical ID of the Fimea marketing authorisation register

VNR-numero [0..1]
Nordic product number. Unique package number. The majority of packages on sale have this ID information.

VanhaVNR [0..*]
List of possible old VNR numbers of a package.

Pakkauskokoteksti
Package size in a “non-structural” format.

Pakkauskokokerroin [0..1]
Package size multiplier (2): e.g. 2 x 10 pcs.

Pakkauskoko [0..1]

Package size (10): e.g. 2 x 10 pcs.

Pakkauskokoyksikko [0..1]
Package size unit (pcs): e.g. 2 x 10 pcs.

Reseptistatus [0..1]
Does the package require a prescription? R = prescription, K = OTC product (self-medication).

JulkinenTarkenne [0..1]

Specifier of package e.g. “Hospital package”.

Annostelulaite [0..1]
Does the package include an administration method, e.g. “oral syringe”.

Sailytysastia [0..1]
Storage container, e.g. “injection bottle”.

Suljin [0..1]
Package closure, e.g. “screw cap”.

SaatavuushairioTiedot
The information listed in the shortage search is based on the information provided by the pharmaceutical company. The listed duration of the shortage is based on the assessment of the pharmaceutical company and the pharmaceutical company is responsible for updating the duration of the shortage if changes occur.

Saatavuushairio
Is there an active shortage of the package: yes(1)/no(0).

SaatavuushairioAlkupaiva [0..1]
Estimated shortage start date.

SaatavuushairioLoppupaiva [0..1]
Estimated shortage end date.

SaatavuushairioIlmoituspaiva [0..1]
First reported day of shortage.

SaatavuushairioMuokkauspaiva [0..1]
Latest reported day of shortage.

SaatavuushairioSyy [0..1]

Not in use for now.

SaatavuushairioLisatietojenAntaja [+..1]
Contact information of marketing authorisation holder.

Kaupanolo
Availability of package on the market.

Kaupan
Is the package for sale: yes(1)/no(0).

Kauppaantulopaiva [0..1]
Latest introduction to market date of package.

Kaupastapoistumispaiva [0..1]
Withdrawal from market date of package.

Pakkaus_Laakeaine [1..*]
Package-Medicinal substance -relation, one or more “Laakeaine” is connected to each package.

Laakevalmiste [0..*]
Information on medicinal product.

Kauppanimi
Valid trade name of medicinal product on run date.

EdellinenKauppanimi [0..*]
Previous trade names since the decision date of the marketing authorisation.

ATCTUN [0..1]
Technical id of the ATC code in Fimea’s database.

ATC-koodi
The Anatomical Therapeutic Chemical (ATC) classification system classifies medicinal products according to which organ or system they affect and according to their chemical, pharmacological and therapeutic properties.

Vahvuus [0..1]
Strength information of medicinal product.

Laakemuoto

Pharmaceutical form of product, e.g. “tablet, film-coated”.

Antoreitti [0..*]
Route of administration of medicinal product, e.g. “Orally”.

Vaikainelkm [0..1]
Number of active substances. Not in use.

DDD [0..1]
Defined daily dose (DDD); defined daily dose amount.

DDDyksikko [0..1]
Defined daily dose (DDD) unit.

HUM
Medicinal product for human use.

VET
Veterinary medicinal product.

Maaraamisehto [0..*]
Describes restrictions on prescribing a medicine. Prescription condition code, reference key to prescription condition code set. For example E139.

Huume [0..1]
H=drug, HE=Actual narcotics that require a separate Fimea permit each time (in connection with time-limited special permit). Huume indicates if the medicine is classified as a drug.

PKV [0..1]
PKV medicines are mainly ones affecting the central nervous system. P=PKV medicine, PA=PKV medicine. Only with an original prescription. Z=PKV medicine, psychotropic substance (lists III and IV), ZA=PKV medicine, psychotropic substance (lists III and IV). Only with retained prescription.

Liikennevaara
1=yes, 0=no. Traffic danger refers to whether the product may impair the user’s ability to drive and use machines.

Lastenlaake [0..1]

Not currently in use

Biologinen
Biological medicinal product.

Plasmaperainenvalmiste
Plasma-derived medicinal products are products in which the active ingredient is derived from human blood or plasma.

Substituutioryhma [0..1]
Grouping for generic substitution i.e. interchangeable medicines. Medicinal products with the same substitution group are interchangeable with each other. The substitution group is issued on the medicinal product level and duplicated for the packages. Fimea does not comment on the interchangeability of the package sizes of medicinal products in the same substitution group.

Velvoitevarastointi
The purpose of the legislation concerning mandatory reserves is to ensure the availability of and access to medicines in circumstances in which usual availability in Finland is restricted or suspended as a result of supply disruptions, a serious crisis or other equivalent reason.

Lisaseurannassa
Additional monitoring is required when there is less information available about the medicine compared with other medicines, for example because it is new on the market or there is limited data on its long-term use.

Biosimilaari
A biosimilar is a biological medicine developed to be similar and comparable to a biological reference medicine. Biosimilar group information is derived from the LaakeRyhmat record

Kohdeelainlaji [0..*]
Target animal species of veterinary medicine.

Elainlaji [0..1]
Target animal species.

Elainlaji-ATC-koodi [0..1]
ATC classification of target animal species.

Elainlaji-Antoreitti [0..*]
Route of administration of medicinal product for animal species in question.

Varoaika [0..*]
Withdrawal period refers to the minimum period of time from administering the last dose of medication and the use of meat or other animal-derived products for food.

Varoaika-elainlaji [0..1]
Animal species for withdrawal period.

Kudos-toimenpide [0..1]
Tissue/Procedure: a production animal product or procedure related to a production animal. E.g. chicken egg or slaughtering.

Varoaika-annostus
Dose size e.g. “40 mg/kg single dose”.

Varoaika-antoreitti [0..1]
Route of administration related to withdrawal period.

Aika [0..1]
Duration of withdrawal period. If withdrawal period = 99, see additional information.

Varoaika-yksikko [0..1]
Unit of withdrawal period duration. E.g. “hours”.

Varoaika-lisatieto [0..1]
Additional information for withdrawal period.

LaakeRyhmat [0..1]
Possible group information for medicinal product.

LaakeRyhma [1..*]
Group information, e.g. Biosimilar group “G001”

Marketing authorisation > Special permit > Registration > Cancelled authorisation

Myyntilupa

Haltija
Name of marketing authorisation holder.

Lupanumero
Marketing authorisation number issued by Fimea. Centralised procedure products do not have this authorisation number, see eumyyntilupanro. For time-limited special permits, it is a technical identification number.

Tila
Status of marketing authorisation. 5=Marketing authorisation approved, 6=Marketing authorisation cancelled by the applicant, 7=Marketing authorisation cancelled by the authorities, 8=Marketing authorisation suspended, 9=Sale prohibited by the authorities, 10=Sale suspended by the holder, 11=Time-limited approval for compassionate use, 12=Time-limited approval for compassionate use ended.

Markkinoija [0..*]
Not in use.

RinnakkaisTuonti
1=yes, 0=no. Parallel import indicates whether a medicinal product is a parallel-import product.

RinnakkaisJakelu
Parallel distribution is the distribution of a medicine granted marketing authorisation centrally by the European Medicines Agency (EMA) from another EU member state by a pharmaceutical company independent of the marketing authorisation holder. EMA authorisation is required for parallel distribution.

EU-lupanumero [0..1]
Marketing authorisation number issued by the EU Commission to centralised procedure products. e.g. EU/1/20/1528/002.

Prosessi
National/Centralised/Decentralised/Recognition

Myontamispaiva [0..1]
Marketing authorisation date of issue.

Paattymispaiva [0..1]
Marketing authorisation end date. Date can also be in the future.

Erityislupa
Time-limited special permit for compassionate use

Haltija
For time-limited special permits, this field mainly contains the manufacturer's name.

Lupanumero
Technical number

Tila
Granted / cancelled

Myontamispaiva [0..1]
Authorisation date of issue

Paattymispaiva [0..1]
Authorisation end date.

Ehto [0..1]
Condition for time-limited special permit.

EhtoSv [0..1]
Condition for time-limited special permit in Swedish.

Rekisterointi
Registrations include traditional herbal medicinal products, homeopathic and anthroposophical products.

Haltija
Registration holder's name.

Rekisterointinumero
Registration number issued by Fimea.

Tila
Registration approved / cancelled.

Prosessi
Registration application process. National/Decentralised/Recognition

Myontamispaiva [0..1]

Registration issue date

Paattymispaiva [0..1]
Registration end date. Date can also be in the future.

RajattuMaaraamisoikeus [0..*]
Not in use for now.

Laakeaine [0..*]
Medicinal substance level

VaikuttavaAine [0..*]
Active substance of medicinal product. Excipients are not listed

Laakeainetunnus
Technical ID from Fimea marketing authorisation register.

Aine
Name of active substance in English.

CASnumero [0..1]
CAS ID (Chemical Abstract Service) is a US-based chemical ID number system.

Maara [0..1]
Amount of active substance in product.

Maarayksikko [0..1]
Amount unit, e.g. mg.

JakamatonVahvuus [0..1]
Expressly written strength if structural strength is not available.

MaaraMin [0..1]
Minimum amount of active substance when amount is reported as a range.

MaaraMax [0..1]
Maximum amount of active substance when amount is reported as a range.

VastatenMaara [0..1]
Amount of active substance in pure form.

VastatenAine [0..1]
Active substance in pure form.

VastatenCASnumero [0..1]
Substance CAS ID.

Laake75 [0..1]
Classification information from Meds75+ database on the suitability of the active substance for older people. One medicinal product can have several active substances with different M75+ classifications. In this case, the classification of the product is determined by the poorest suitability.

Luokka
A, B, C, D

KommenttiFI
Comment in Finnish on suitability for older people.

KommenttiSV
Comment in Swedish on suitability for older people.

KommenttiEN
Comment in English on suitability for older people.

LuokitteluPvm
Latest check date of Meds75+ classification.