

Drug dosage forms and routes of administration

Information about drugs

Drug legislation in CZ

What is a dosage form?



It is a final form, in which the drug is given to the patient.

Dosage Form

- Mixture of **substances with therapeutical effect** and **excipients**
 - Excipients: antioxidants, fillers, pigments (dyes), fragrances, ointment bases, solvents etc.
 - No pharmacological effect
 - Allergies (parabens), intolerance (lactose)
- **Shape** and **characteristics** of a medical preparation
- Adjusted to the **route of administration**
- Influence **pharmacokinetics** of a medical substance

Generations of dosage forms:

1st = classic dosage forms

2nd = controlled release

3rd = controlled biodistribution

Excipients of AERIUS tablets:

Core: calcium hydrogen phosphate dihydrate, microcrystalline cellulose, maize starch, talc.

Coating: lactose monohydrate, hypromellose, titanium dioxide, macrogol 400, indigotin, carnauba wax, white wax.

Classification of Dosage Forms



According to the consistency:

- solid
- semi-solid
- liquid
- gaseous

According to the usage:

- **for internal use** (*Ad usum internum*, e.g. *Peroralia*, *Parenteralia*)
- **for other use** (*Ad usum alium*, e.g. *Ocularia*, *Nasalia*, *Unguenta*).

Liquid Dosage Forms

a) For internal use:

1. (Per)oral liquids

- solutions, suspension, emulsion for *per os* administration
- tinctures, drops, syrups

2. Parenteral liquids

- injections
- infusions



b) For external use:

- eye drops, ocular waters, ear drops, nasal drops
- liquids for cutaneous use, for compresses
- liquids applied to the mucosa (douche – irrigation, gargle)

Semi-solid Dosage Forms

- Applied on the **skin** or **mucosa**
 - Local effect (dermatology)
 - Systemic effect (TTS)



- Ointment (unguent)
- Creme
- Gel (jelly)
- Paste
- Transdermal patch (TTS, *Emplastra*)



Solid Dosage Forms

Specific in shape:

- Tablet
- Suppository
- Vaginal pessary (suppository)
- Capsule
- Lozenge (pastilles)

Non-specific in shape:

- Dusting powder
- Herbal mixture
- Peroral powder:
 - Classic
 - Grained
 - Effervescent



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Tablets and Capsules

Tablets:

- Uncoated
- Coated
- Gastro-resistant
- Effervescent
- Tablets dispersed in the mouth
- Chewable
- Sublingual
- etc.



Capsules:

- Hard
- Soft
- Gastro-resistant
- With modified release
- etc.



Gaseous Dosage Forms = Aerodispersions

Topical

- ear, nasal, oral, sublingual and cutaneous spray

Preparations for inhalation

- liquids (scattering of liquid drops)
- powders (particle size determines the place of absorption)

Foams

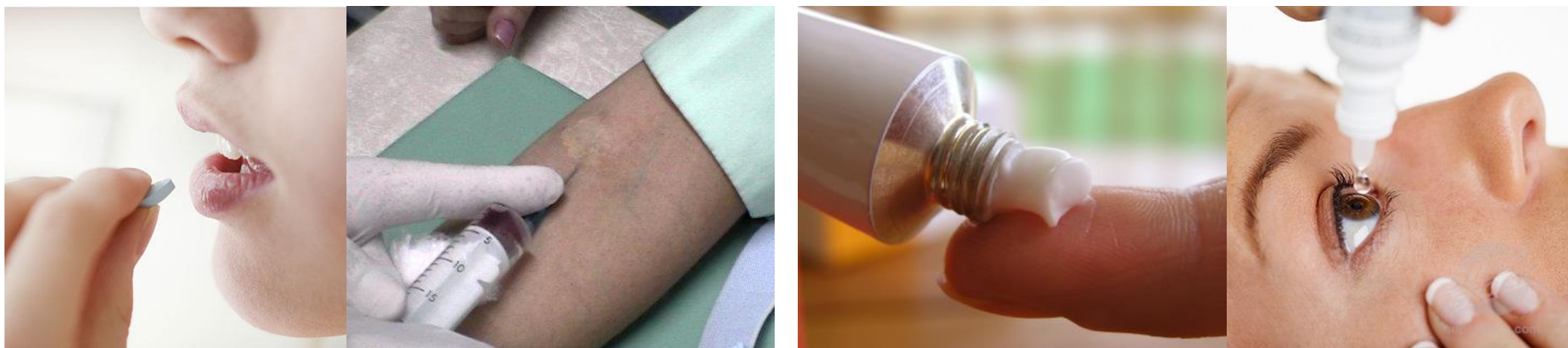
- cutaneous, rectal, vaginal foams

Making of an aerodispersion:

- Mechanically by a nebulizer (spray ,
- By liquefied/compressed gas (pressure container)



How could a drug be administered?



Routes of administration

Systemic administration
= drug is **absorbed** into the **circulation** → it influences all the body

- enteral
- parenteral

Local (topical) administration
= drug is **NOT absorbed** into the circulation → it affects only the place of application

- skin, mucosa, e.g. conjunctiva
- GIT, but the drug is not absorbed from GIT

Systemic administration – enteral

(Per)oral (*per os*, p.o.)

Enteron (ancient greek) = intestine

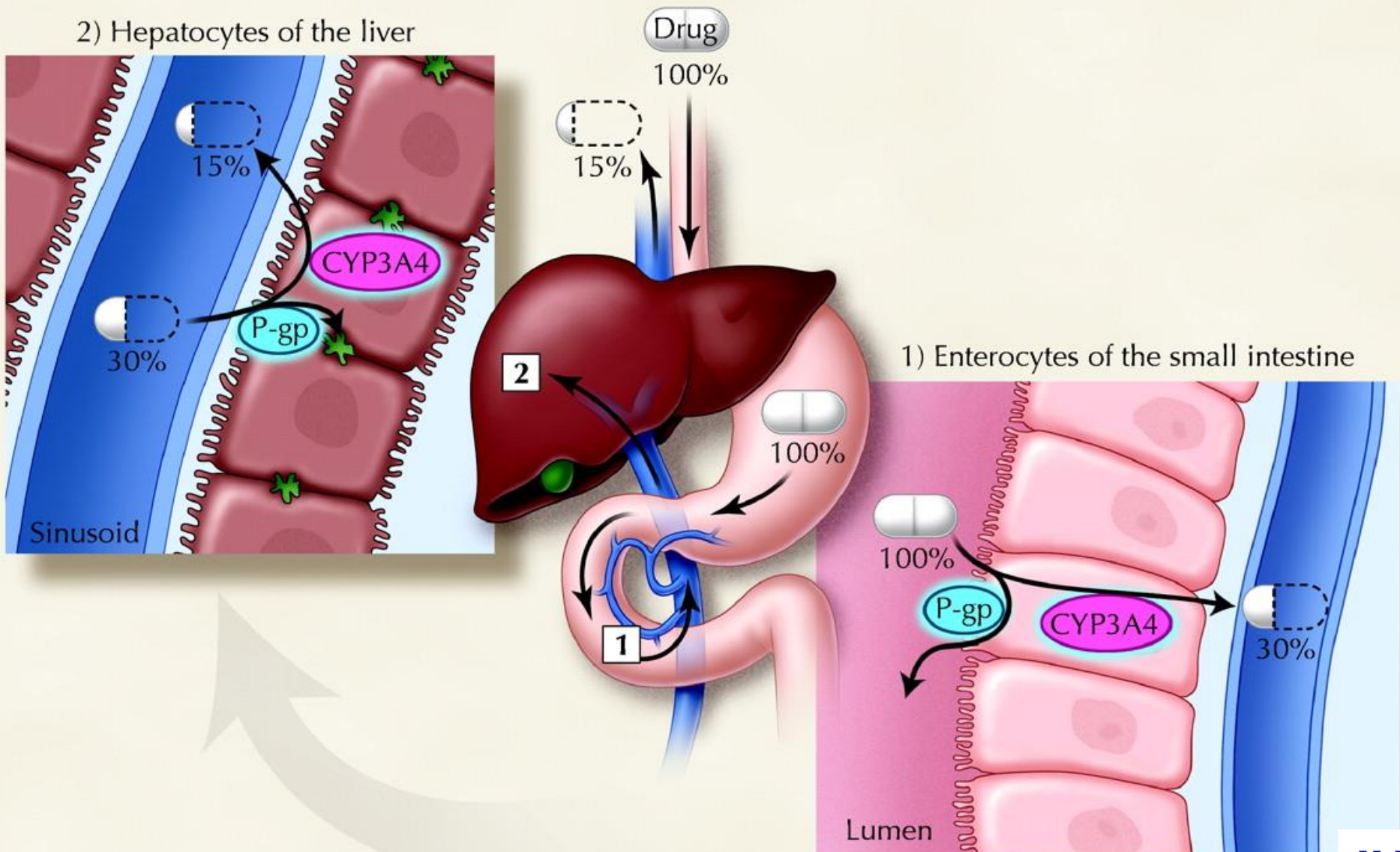
- Onset of effect depends on phys-chem. properties of the medical substance and excipients
- Possibility of lower bioavailability: first-pass effect (liver)



Rectal (*per rectum*)

- Do not irritate stomach, do not cause nausea
- Lower bioavailability – lesser surface of rectum walls
- Sooner onset of effect – *plexus venosus rectalis* flows into *vena cava inferior* („bypass of the liver“)

„First pass“ effect



Systemic administration – parenteral

Para enteron (ancient greek) = out of the intestine

1. Non-injection (non-invasive)

a) oral

- Absorption by oral mucosa (e.g. sublingual)
- Lipophilic substances – quick absorption (2 mins), e.g. nitroglycerin

b) inhalation

- Gases, vapours nebo small particles
- Respiratory diseases (asthma, COPD...)

c) transdermal

- TTS = transdermal therapeutic system (controlled release)
- E.g. hormonal contraception patch, nicotine patch, analgesic patch

d) transnasal

- Good perfusion of nasal mucosa
- Substances could irritate it, or impair cilia function
- E.g. calcitonin, antimigraine drugs

e) vaginal – e.g. hormonal contraception ring



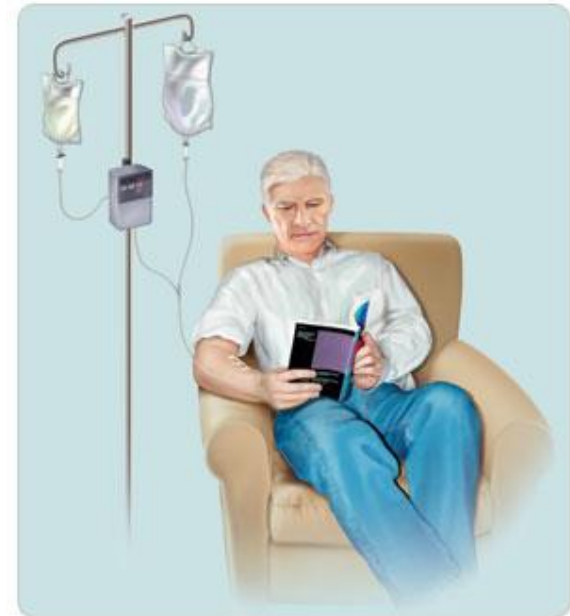
Systemic administration – parenteral

2. Injection (invasive)

- non-physiological

a) injection

- small volume of liquid
- i.v. administration – quick onset of effect
- i.m., s.c. – gradual absorption into circulation



b) infusion

- larger volume of liquid
- parenteral nutrition, minerals, glucose, ATBs, cytostatics etc.



Could this drug influence the effect of other drugs?



What is this tablet?

How frequently should I use it?

What is this drug used for?

How to store it?



What are possible adverse effects?

What is an appropriate dose?

Does it influence vigily?



Who must not use it?



Information about Drugs

PIL & SPC

- PIL = patient information leaflet = package leaflet **for patients**
- SPC = summary of product characteristics = information **for medical specialists** (physicians, pharmacists, nurses etc.)

EMA – **European Medicine Agency** (ema.europa.eu)

- Database of RMPs granted central authorisation by EC/EMA
- Reports concerning drugs' safety – **alerts**
- List of **newly authorized drugs**

SUKL – **State Institute for Drug Control** (sukl.eu)

- Database of RMP authorized in CZ
- Free access to all PILs and SPCs (in czech)

European Pharmacopoeia = european standard for the quality of drugs (**Czech Pharmacopoeia** = text from EP + czech specialities)

Computer databases of medical preparations

- **AISLP** (czech↔english, in most pharmacies and doctor's offices)

Pharmacopoeia

- Purpose: **to guarantee safe, effective and quality drugs**
- Information about medical substances, excipients, dosage forms
- Instructions for production, preparation, control, storage of drugs
- Used mostly in pharma industry

What could we found there?

- Analytical and instrumental **examination methods**
- **Materials** for drug containers and cases
- Instructions to ensure **sterility** of medical preparations
- Instructions concerning **radiopharmaceuticals, vaccines** etc.
- **Monographs** of specific substances
- Tables with usual **dosage of drugs** in adults, children, animals
- etc.

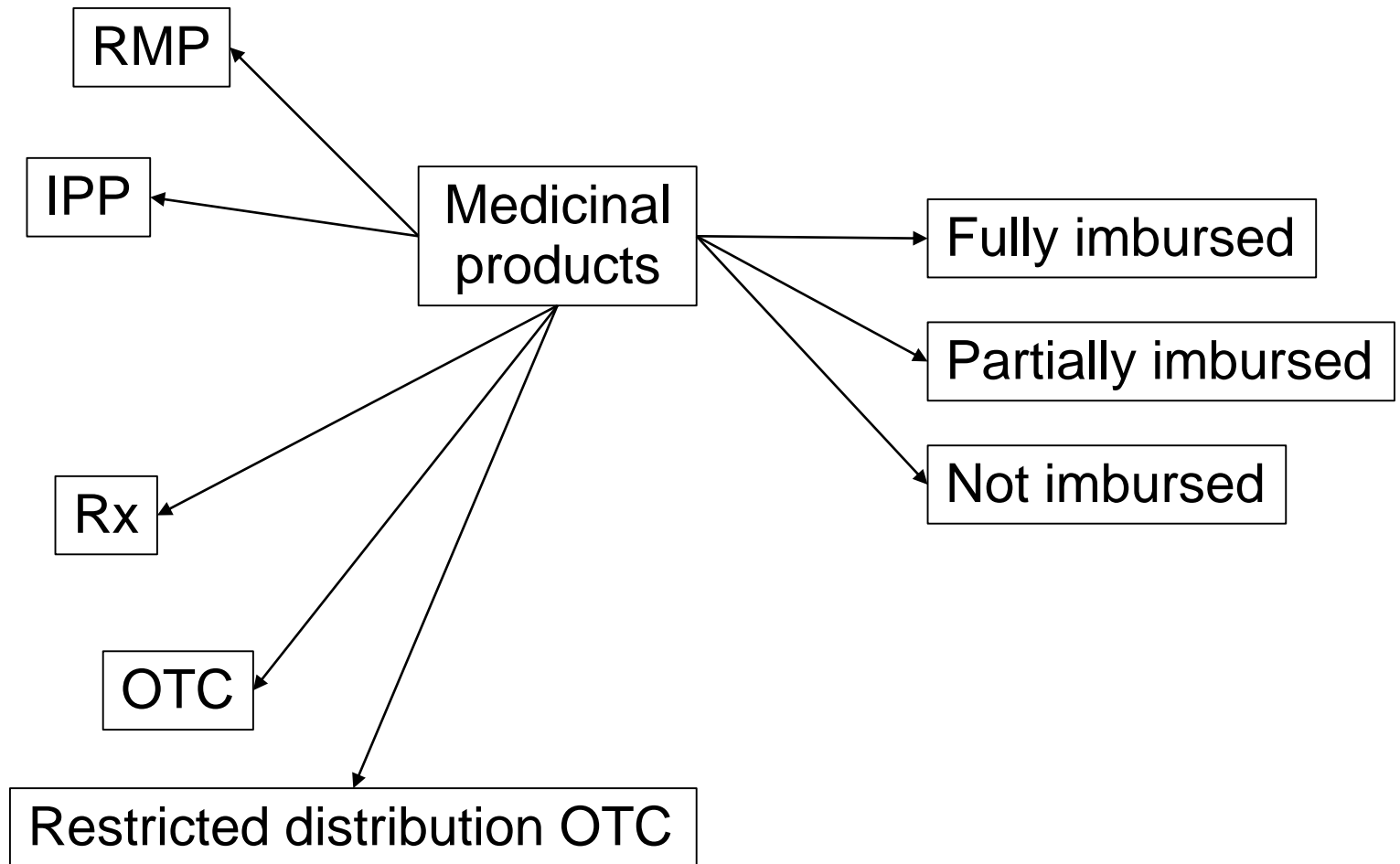
NO: mechanism of actions, adverse effects, pharmacokinetics, contraindications, pregnancy safety etc.!

Basic Drug Legislation in CZ

Act No. 378/2007 Coll., on pharmaceuticals

- Research
- Authorization of new drugs („registration“)
- Production, preparation and distribution
- Prescribing and dispense of medical preparations
- Destroying of unusable drugs
- Pharmacy duties
- **Pharmacovigilance** = drug safety service
- Controls and sanctions

TYPES OF MEDICINAL PRODUCTS

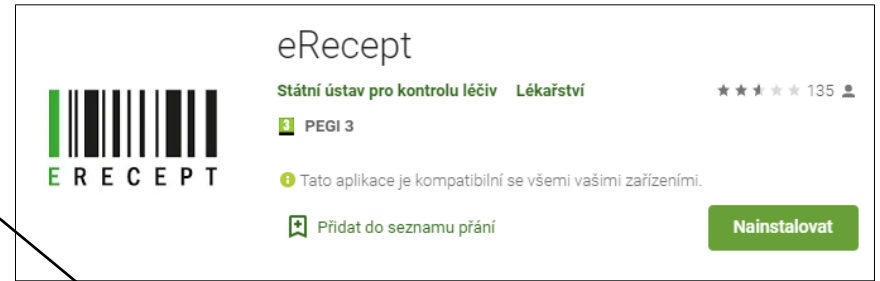


e-Rx TYPES

e-Rx on ID card



e-Rp App



E-mail

Paper „dispatch note“

e-Rp by sms



Pacient: Jana Příkladná * 5. 5. 1950 ZP: 111
Vystavení eRp: 1.1.2018 Platnost eRp: 15.1.2018

Lékař: MUDr. Jan Příkladný
Tel.: 555 555 555

PCIF F8GN BL23



PALENRA 500, TBL NOB 24 x 500MG

Množství: 1x

Úhrada: pacient

Dávkování 1-0-0

PAPER Rx

- Exceptional, only in justified cases
- **Not for repeated use**
- Pharmacist needs to **digitalize** it – record into the e-Rx system
- Only 1 type of medicine
- Valid without doctor's stamp, but the identification of the doctor need to be present („IČZ“ – identification number of medical facility)
- **Which situations can justify the use of paper Rx?**
- Obligatory – specified addictive substances (Rx „with blue strip“)

OVERVIEW OF RX VALIDITY

- **e-Rx**
 - 14 days + day of issue
 - Doctor can extend validity up to 1 year, pharmacist can add another 14 days
- **Emergency** – end of the day following the day of issue
- **Rx for repeated use** – 6 months, max 1 year
- **Paper Rx** – 14 days + day of issue
- **Rx „with blue strip“** – 14 days + day of issue; extension up to 30 days

Medical Prescription (Rx) in CZ

Kód pojišťovny 211	RECEPT		poř. č.
Udaje platné pro celý recept (výpis, pohotovost, repatur s počtem opakování, nutná a neodkladná péče, atd.)			
Příjmení a jméno Zbořil Roman			
Číslo pojištěnce	810412/4149	f.	
Bydliště (adresa) Budovatelská 4804 , 760 05 Zlí			
0146034			
Popl.	Diagnóza *)	Sk.	Kód
Rp. QUETIAPIN MYLAN 200 MG POR TBL FLM 60x200 MG EXP. ORIG. No.II / DUAS / D.S. 0-0-1			
0066555			
Popl.	Diagnóza *)	Sk.	Kód
Rp. MAGNOSOLV POR GRA SOL 30 <i>exp. 1x + nová kúra muj/po/s</i>			
Dne: 27.12.2014			
			
razítko poskytovatele, jmenovka, podpis a telefon lékaře		Připravil:	Vydal:

Kód pojišťovny	RECEPT		poř. č.
série OU			
Příjmení a jméno			
Číslo pojištěnce			f.
Bydliště (adresa)			
Rp.			Cena
Sk.	Kód		
Rp.			
Sk.	Kód		
Dne:			
razítko zdrav. zařízení, jmenovka a podpis lékaře			Připravil:
			Vydal:

ADDICTIVE SUBSTANCES

- Prescription according to the substance classification (Gov. Reg. No. 463/2013, on the List of addictive substances – Appendices 1-8)

Rx „with blue strip“

- Appendix 1 + 5 = **narcotics** (list I), **psychotropics** (list II) specified in Single Convention on Narcotic Drugs (1961), and Convention on Psychotropic Substances (1971)
- Rx is a **paper form**, 3 pages (1 original, 2 copies)
- 1 Rx = 1 type of medicine
- Specimen of the form is stated in legislation
- Validity 14 days + day of issue

Legislation – Drugs of Abuse

Pořadové číslo tiskopisu		Kód obecního úřadu obce s rozšířenou působností *)	
Kód zdravotní pojišťovny:	Recept na léčivé přípravky obsahující omamné látky seznamu I a psychotropní látky seznamu II		
Jméno a příjmení:			
Číslo pojištěnce:		Datum narození:	
Adresa:		Telefonní číslo pacienta:	
Rp.		Úhrada pojišťovnou Kč	
Datum:		Razítko poskytovatele Jmenovka* a podpis Předepisujícího lékaře	
Celkem Kč			
Přijal:	Připravil:	Vydal:	Poř. č.