

Medicines and Driving on Public Roads in Romania

Risks, warnings and the role of specialist medico-legal assessment

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A correctly prescribed medicine can treat an illness while temporarily reducing a person's ability to drive. Drowsiness, slower reactions, visual disturbances and low blood glucose are relevant to road safety even when treatment is taken at the recommended dose. Conversely, simply identifying a substance in the body does not, by itself, resolve the legal question of driving under the influence. [1–3, 13–28]

A proper assessment distinguishes the effects of treatment, the underlying illness, medical fitness for a driving licence and potential criminal liability. These issues overlap but follow different criteria and procedures.

1. Three questions that must be distinguished

Question	What must be assessed?	Who is involved?
Can I drive safely after this dose?	Product effects, timing, individual reactions and combinations	The treating physician and pharmacist, using the leaflet and SmPC
Am I medically fit for my licence category?	Illness, symptom control, treatment and category-specific risks	Authorised medical facilities under road traffic regulations
Was the detected substance capable of affecting driving at the relevant time?	Toxicological, clinical and circumstantial evidence, interpreted individually	Specialist medico-legal assessment; the legal decision belongs to the judicial authorities

SmPC means Summary of Product Characteristics, the professional document accompanying a medicine's authorisation. Section 4.7 addresses effects on driving and operating machinery. Patients can find the corresponding information in the package leaflet. [4–6, 12]

2. The Romanian legal framework

Medical fitness to drive

Government Emergency Ordinance No 195/2002, particularly Article 22, governs medical and psychological examinations and procedures concerning fitness to drive. Minister of Health Order No 1,162/2010 approves the minimum standards of physical and mental fitness. Its section on drugs and medicines covers treatments and combinations that affect driving. Additional risks for Group 2 must be considered separately. [3, 4]

Group 1 includes, among others, categories A and B, while Group 2 includes categories C and D and their associated subcategories. Classification by licence category must be distinguished from additional obligations arising from professional driving. A prescription does not replace a fitness assessment and does not, in itself, authorise driving. [3, 4]

Criminal liability

Article 336(2) of the Romanian Criminal Code penalises driving a vehicle requiring a licence while under the influence of psychoactive substances. In the version reviewed, the basic penalty, by reference to paragraph (1), is imprisonment for one to five years and disqualification from exercising certain rights; paragraph (3) provides an aggravated form for specified circumstances. [1]

In Decision No 25/2025, the High Court of Cassation and Justice held that two elements must be established cumulatively: the presence of the psychoactive substance in biological samples and its capacity to potentially impair driving ability. This binding interpretation means neither that a positive test automatically establishes an offence nor that an accident or striking clinical manifestations must necessarily have occurred. The absence of obvious clinical signs does not, by itself, determine the case. [2]

Lawful use of a medicine may be relevant to the case, but a prescription is not a general exemption from Article 336(2). Equally, not every adverse reaction that makes driving unsafe should automatically be classified as driving under the influence of a psychoactive substance. Hypoglycaemia and blurred vision, for example, first require medical assessment of the specific mechanism. Legal classification belongs to the judicial authorities. [1, 2, 25, 26]

3. The European framework: fitness, information and legislative transition

Annex III to Directive 2006/126/EC on driving licences sets minimum medical requirements, including those concerning psychotropic substances and medicines. The principle is to protect safe driving, including where medicines or combinations that affect driving ability are used regularly. Romania transposed this framework through Order No 1,162/2010. [3, 7]

Directive (EU) 2025/2205, adopted on 22 October 2025, introduces the new European driving licence framework. The general timetable provides for transposition by 26 November 2028 and application from 26 November 2029, alongside specific provisions and deadlines. In October 2026, entry into force must not be confused with immediate full application of all the new rules in Romania. [8]

For medicines, authorised product information uses section 4.7 of the SmPC, where effects on driving may be described as absent/negligible, minor/moderate or major. These pharmacological descriptions are not, in themselves, categories of criminal offences. National rules on establishing and penalising driving under the influence must be considered separately. [1, 12]

4. What do medicine-related triangles mean?

The red triangle: a warning with a specific legislative history

In Romania, Order No 759/2003 supplemented Order No 87/2003 with a distinctive symbol for the outer packaging of medicines contraindicated for drivers: an upright triangle with a red border, white background and black exclamation mark. [9]

An essential legal qualification is that Order No 87/2003, including its amendments and additions, was expressly repealed by Article 4 of Order No 1,162/2010. The old order and its list should therefore not be presented as a current legal basis. The history of this symbol also does not establish that every relevant medicine today must carry such a mark on its packaging. [3, 9]

In practice, packaging warnings should be taken seriously, but their absence does not certify safety behind the wheel. Check the exact product, including active substance, strength and pharmaceutical form, against its current leaflet and SmPC available through the Romanian medicines agency, ANMDMR. [12, 29]

Symbol or information	Meaning	How to use it
Red-bordered triangle with an exclamation mark	Driving-related warning; the Romanian 2003 regulation is historical and was subsequently repealed	Check the specific warning and current product information
Solid black inverted triangle	Additional pharmacovigilance monitoring	Does not automatically mean a driving prohibition
Driving section in the leaflet	Authorised advice for patients	Read it in full and consider medical advice
Section 4.7 of the SmPC	Assessment of effects on driving and operating machinery	A professional reference, alongside warnings and interactions

The black triangle is regulated at European level by Commission Implementing Regulation (EU) No 198/2013. It appears in the leaflet and SmPC of medicines subject to additional monitoring. It is not a European pictogram for a medicine prohibited while driving, and does not, by itself, indicate that a product is unsafe. [10, 11]

Nordic countries: one red triangle, rather than three risk colours

The Danish Medicines Agency describes the use of a red warning triangle in Denmark, Norway, Finland and Iceland. In the Danish system it identifies medicines that may significantly affect driving or operating machinery. The authority distinguishes degrees of influence, but the described packaging symbol is a single red triangle, rather than a sequence of yellow, orange and red triangles. Absence of the triangle does not exclude impairment. [31]

France: three levels on yellow, orange and red backgrounds

The French system is a national packaging regulation, rather than merely a research project. The order of 8 August 2008 provides for a pictogram showing a car inside a triangle, with a coloured background, a numerical level and a message. The colours refer to the background of the pictogram. The recommendations below convey the meaning of the French messages in English. [32]

Level and colour	Practical meaning	Advice to users
Level 1 - yellow	Caution is necessary	Read the leaflet before driving
Level 2 - orange	Greater caution is necessary	Do not drive without advice from a healthcare professional
Level 3 - red	Danger for driving	Do not drive; seek medical advice before resuming driving

These levels should not be assigned intuitively to every medicine in a class. The marking concerns the product and its classification within the applicable system; it cannot automatically be converted into a criminal-law classification in Romania. [1, 32]

The European DRUID project: a four-category risk scale

The DRUID project (Driving under the Influence of Drugs, Alcohol and Medicines) also studied communication of medicine-related risks. One pictogram model uses a green-yellow-orange-red scale, categories 0 to 3 and an indicator bearing a car symbol. Project materials describe testing pictogram models among patients in Spain and the Netherlands. This is a European research and risk-communication scheme, not a mandatory, harmonised labelling system for all medicine packaging throughout the EU. [33, 34]

DRUID category and colour	Influence on driving	Interpretative limitation
0 - green	Absent or negligible	Not an individual guarantee of safety
1 - yellow	Minor	Check product information and individual reactions
2 - orange	Moderate	Requires greater attention and assessment of driving conditions
3 - red	Severe	Indicates a substantial potential for impairment

A recollection of multicoloured medicine warnings may therefore relate to the French system or the DRUID model. These should be distinguished from the Nordic red triangle and the European black triangle for additional monitoring. For a patient in Romania, the practical reference remains the exact product's leaflet, together with advice from the physician and pharmacist. [10–12, 31–34]

5. Forensic medicine provides specialist expert assessments

Forensic medicine is not limited to collecting samples or reporting a toxicological result. Expert assessment to establish intoxication with psychoactive substances or driving under their influence is provided for in Article 33(7) of the procedural rules approved by Order No 1,134/C/255/2000. Its reference to paragraph (3) specifies a commission within a forensic medicine institute, comprising a senior forensic physician and a senior pharmacist or toxicologist from the institute's laboratory, both holding expert status. [5]

Article 10 of the rules approved by Order No 5,870/2024 provides that an ordered expert assessment is undertaken only after confirmatory toxicological analyses have been completed, and by forensic medicine institutes. Sample collection and handling are regulated by Government Decision No 877/2024. The toxicological rules were amended by Order No 3/2025. [6]

Stage	What it can establish	Main limitation
Roadside rapid testing	A screening result for the substances or classes targeted by the device	Not an expert assessment of influence; performance depends on the test
Preliminary laboratory analysis	Presence or absence of substances in the samples using the methods employed	Must not be confused with individual medico-legal interpretation
Toxicological confirmation	Substance identity and analytical findings required for interpretation, including relevant quantitative measurements	Concentration alone does not provide the legal verdict
Medico-legal expert assessment	Significance of the findings for the relevant time and questions investigated	Depends on the quality of samples and available information

According to the position of the Superior Council of Forensic Medicine (CSML), interpretation requires comprehensive toxicological determinations, including quantitative testing, correlated with clinical and investigative information. Relevant factors include the substance and metabolites; the times of administration, driving and sampling; doses; coexisting illnesses; and other substances consumed. Simplistic retrospective calculations by analogy with alcohol are not justified. [13]

The assessment must distinguish analytical presence from a relevant pharmacological effect and explain the limits of its conclusions. An inactive metabolite does not have the same significance as the active substance;

urine and blood do not provide identical temporal information. The analytical threshold of a method must not automatically be treated as a universal road-safety threshold. Tolerance and a concentration falling within a therapeutic range do not, by themselves, guarantee safe driving. [13]

Prescriptions, medical letters and records specifying administration are useful. If medicines were given by an ambulance team or in hospital after the event, the chronology must be documented: subsequent administration cannot automatically be attributed to the earlier time of driving. The scientific report supports the assessment of evidence without replacing the judicial decision. [1, 5, 13]

6. Medicines requiring attention: tables by category

The following tables are illustrative and non-exhaustive. The substances and products listed are not treatment recommendations, a statutory prohibition list or an automatic classification for drug-screening tests. Effects vary between products, doses and individuals. Current authorised product information and individual assessment take precedence for each medicine.

A. Sedatives, hypnotics and centrally acting analgesics

Category and examples	Driving-related risk	Essential precaution
Benzodiazepines: alprazolam, diazepam; brand examples: Xanax, Diazepam Terapia [14, 15]	Drowsiness, reduced concentration and slower reactions; effects enhanced by alcohol and other sedatives	Do not drive until individual effects are known and leaflet conditions are met; do not drive if impaired
Hypnotics: zolpidem [16]	Next-morning impairment, reduced alertness and complex sleep behaviours	Allow at least 8 hours between a dose and activities requiring alertness; this does not guarantee safety if symptoms persist
Hypnotics: zopiclone [17]	Residual sedation and psychomotor impairment	The SmPC particularly warns against driving during the first 12 hours; follow the exact product's instructions
Barbiturates: phenobarbital [18]	Sedation and reduced alertness, worsened by combinations	Treatment and the underlying condition require medical assessment; do not abruptly stop treatment in order to drive
Opioids: tramadol and combinations with paracetamol [19]	Drowsiness and dizziness; enhanced effects with alcohol or central nervous system depressants	Do not drive if affected; reassess when starting, changing the dose or adding another sedative
Codeine and analgesic/antitussive combinations [20, 30]	Possible impairment of alertness; combining codeine with paracetamol or ibuprofen does not remove the risk	Check all active ingredients; a familiar analgesic brand does not guarantee identical composition

The Ministry of Health's information list includes other opioids, such as morphine, fentanyl, oxycodone, methadone and buprenorphine. It also includes benzodiazepines, hypnotics, gabapentinoids and certain stimulant medicines. Its purpose is risk information; it does not replace the leaflet or individual assessment. [30]

B. Neurological and psychiatric treatments

Category and example	Relevant risk	Key point
Gabapentinoids: pregabalin; gabapentin also appears in the Ministry's list [21, 30]	For pregabalin: dizziness, drowsiness and reduced concentration	Do not drive until individual effects are known; assessment is also needed when prescribed for neuropathic pain
Antidepressants: mirtazapine [22]	Reduced attention and concentration, particularly at initiation	Avoid hazardous activities when affected; do not assume identical effects across all antidepressants
Antipsychotics: quetiapine [23]	May affect activities requiring mental alertness	Avoid driving until individual sensitivity is known; the underlying illness also matters
Dopamine agonists: pramipexole [24]	Drowsiness and sudden sleep episodes	Do not drive if these occur; treatment must be reassessed
Intranasal esketamine: Spravato [28]	Sedation, dizziness and temporary impairment of alertness	No driving until the next day after restful sleep, in accordance with the product information

Use of a psychiatric medicine does not mean that every patient taking it is permanently unfit to drive. Improvement of the illness under treatment does not automatically cancel relevant adverse effects. Decisions should consider clinical stability, the specific product and the requirements of the licence category. [3, 21–24]

C. Common medicines and other mechanisms of impairment

Category and example	Possible mechanism	Practical precaution
Sedating antihistamines: chlorphenamine [27]	Sedation, blurred vision and reduced coordination	Check cold remedies and combinations with other antihistamines
Newer-generation antihistamines: cetirizine [26a]	Drowsiness in some people, although testing at the recommended dose showed no clinically relevant impairment	Do not drive if drowsy; avoid assuming that all antihistamines are identical
Antiemetics: metoclopramide [26b]	Drowsiness, dizziness, dystonia/dyskinesia, with possible visual and motor effects	Do not drive with these symptoms; seek assessment if abnormal movements occur
Insulins; example: insulin glargine [25]	Hypoglycaemia can impair concentration and reactions; hyperglycaemia and visual disturbances may also matter	Fitness requires assessment of disease control and awareness of hypoglycaemia
Alpha-blockers: doxazosin [26c]	A fall in blood pressure, particularly at initiation; possible impairment of driving	Take care when starting or adjusting treatment; do not drive if dizzy or faint
Mydriatic eye drops: tropicamide [26]	Blurred vision and light sensitivity	Do not drive until symptoms resolve; arrange transport after the eye examination

A negative rapid test does not certify fitness to drive under every treatment. A person may be impaired through a mechanism that the test does not assess, such as hypoglycaemia or blurred vision after eye drops. [25, 26]

7. How patients can reduce risk

1. Read the driving section of the leaflet before the first dose and whenever changing product or strength. Check the complete ingredient list. [12, 27, 30]
2. Tell your doctor which licence category you hold and whether driving is a professional activity. Some risks require assessment beyond the usual advice. [3, 4]
3. Do not drive if drowsy, dizzy, inattentive or confused, or if coordination is impaired. Feeling that you have become used to a medicine is not an objective test of safety. [13–28]
4. Avoid alcohol and sedative combinations that have not been discussed with your doctor. Medicines taken separately can interact when used together. [15, 18, 22, 27]
5. Observe the intervals specified in the leaflet. There is no single number of hours valid for all medicines, and disappearance of drowsiness does not guarantee complete elimination of the substance. [13, 16, 17, 28]
6. Do not abruptly stop an important treatment just to drive. Discuss alternatives or dose adjustments with your doctor. [14, 17, 18]
7. If samples are collected, declare all medicines, doses and administration times; retain documents that can clarify treatment. [13]

8. Frequently asked questions

Does a prescription automatically allow me to drive?

No. A prescription justifies treatment, while compatibility with driving is assessed separately. Product warnings, the clinical situation and fitness regulations must be respected. [3, 4]

Is a medicine safe for driving if there is no triangle on the box?

That conclusion cannot be drawn. The leaflet and SmPC are essential, and effects may depend on dose and combinations. The black triangle in the leaflet has a different meaning: additional monitoring. [10–12]

Does a positive rapid test mean that the medicine made me unfit to drive?

The result requires toxicological clarification and contextual interpretation. It is not equivalent to an expert assessment of influence. Analysis under Article 336(2) also requires consideration of the substance's capacity to impair driving, as established by High Court Decision No 25/2025. [2, 6]

How many hours must I wait before driving?

The answer depends on the medicine. Zolpidem, zopiclone and esketamine have different time-related warnings. A minimum interval is not a guarantee if impairment persists or combinations and individual risk factors are present. [16, 17, 28]

Does everyone taking medication need a medico-legal expert assessment?

No. Treatment recommendations and routine fitness assessments follow the applicable medical procedures. A medico-legal assessment of influence is a specialist examination ordered in a judicial context and performed under its own rules. [3–6]

Conclusions

Safe driving during treatment cannot be established from a single pictogram, the existence of a prescription or an isolated result. It requires knowledge of the product and assessment of the individual. In judicial cases, forensic medicine provides specialist interpretation of toxicological, clinical and circumstantial evidence, with explicit scientific limitations. This distinction supports both road safety and sound medico-legal assessment.

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