



## **CATEGORIZATION SYSTEM FOR MEDICINAL DRUGS AFFECTING DRIVING PERFORMANCE**

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**Disclaimer: Although the information presented below has been gathered and evaluated with great care, ICADTS will not accept any liability after use of the information by patients taking the medicines listed**

**Note: The application of the ICADTS list without reading this background information will limit the use of the various advises provided to physicians and pharmacists. Therefore it is strongly recommended to read the full document before using the ICADTS list.**

### **Introduction**

After the publication of the report of the ICADTS Working Group on Prescribing and Dispensing Guidelines for Medicinal Drugs affecting Driving Performance in 2001 (see [www.icadts.org](http://www.icadts.org)), it was discussed that a list with medicinal drugs categorized according to their impairing properties was needed. The practical use of the guidelines would benefit from the availability of such a list, because it would allow the prescribing doctor and dispensing pharmacist to look for safer alternatives within one specific therapeutic class..

### **Descriptions of categories**

Ever since the development of a list according to the impairing properties of medicinal drugs in 1991 (Wolschrijn et. al), three European countries introduced their list based on the original proposal by Wolschrijn et al. Belgium was the first to publish an updated list in 1999, Spain followed in 2002, and France recently in 2005 introduced a more extensive list.

Belgium and Spain applied the original descriptions of the categorizations in their publications, whereas France used a different approach. The original descriptions of impairment of driving performance or performance related to driving as described by Wolschrijn et al. have been summarized in the European Note for Guidance for the Summary of Product Characteristics (III/9163/90-EN, Final approval 16<sup>th</sup> October 1991) for use in the package inserts of medicinal drugs into:

1. Presumed to be safe or unlikely to produce an effect;
2. Likely to produce minor or moderate adverse effects;
3. Likely to produce severe effects or presumed to be potentially dangerous.

Ever since many articles have been published where the practical implications of this three-tier categorization system were illustrated by comparing the effects within the three categories with effect of different blood alcohol concentrations (BAC). Based on experimental work in the Netherlands with over-the-road driving tests the calibration was introduced for

categories I, II and III as respectively equivalent to BACs < 0.5 g/l (<0.05%), 0.5-0.8 g/l (0.05-0.08%), > 0.8 g/l (>0.08%).

It was decided by the experts from the ICADTS working group to use this calibration scheme as part of the clarification of the terminology of the three categories, because this was considered to be more meaningful since 0.5 g/l is the legal limit in the vast majority of EU countries. Although the Belgian categorizations were described as the original and extensive ones as suggested by Wolschrijn et al. in 1991, and used for the purpose to achieve consensus among international experts, it is easier to read the categories by using a more condensed description. This is the case with the Spanish descriptions that are the summarized ones as being used by the EU's Committee for Proprietary Medicinal Products in its Note for Guidance (see above).

The French descriptions are somewhat different because they are considering the perspective of the patient allowing him or her to act and to decide on the best way to respond to the warning given for a specific category. But basically the idea behind it is not so different, it is more focussing on the practical use of the various categories, which is an advantage. It also takes into account the judgement of the physician.

Although these differences in descriptions exist, it is possible to agree on the categorizations based on existing systems in the various countries, and therefore the ICADTS Working Group has proposed the following descriptions for using its list:

Description of category	Interpretation and practical use
<p><b>Category I:</b></p> <p><b>Presumed to be safe or unlikely to produce an effect</b></p>	<p>In various experimental circumstances negligible or no impairment of driving performance or performance related to driving is repeatedly demonstrated. Also for medicinal drugs that are presumed not to be dangerous based on their pharmacological profile, even though there are no experimental studies that support this presumption.</p> <p>For the most frequently used drugs in this category the effect has been assessed in over-the-road driving tests as equivalent to blood alcohol concentrations &lt; 0.5 g/l (&lt;0.05%).</p> <p><u>Advice for the patient:</u> Be careful not to drive before having read the warnings in the package insert.</p>
<p><b>Category II:</b></p> <p><b>Likely to produce minor or moderate adverse effects</b></p>	<p>Some impairment of driving performance or performance related to driving is seen in various experimental laboratory circumstances.</p> <p>Also for drugs that will not produce severely adverse effects, but because of a lack of sufficient experimental studies it can not be established if the effect is moderate, light or absent.</p> <p>For the most frequently used drugs in this category the effect has been assessed in over-the-road driving tests as equivalent to blood alcohol concentrations 0.5- 0.8 g/l (0.05-0.08%).</p> <p><u>Advice for the patient:</u> Do not drive without consulting a healthcare professional about the possible impairing effects.</p>
<p><b>Category III:</b></p> <p><b>Likely to produce severe effects or presumed to be potentially dangerous</b></p>	<p>In various experimental circumstances gross impairment of driving performance, or performance related to driving, is repeatedly seen.</p> <p>Also for drugs presumed to be potentially dangerous based upon their pharmacological profile, but there are not sufficient experimental studies to support this presumption.</p> <p>For the most frequently used drugs in this category the effect has been assessed in over-the-road driving tests as equivalent to blood alcohol concentrations &gt; 0.8 g/l (&gt;0.08%).</p> <p><u>Advice for the patient:</u> Do not drive when this drug is taken and consult a healthcare professional when to start driving again after evaluation of the treatment outcomes.</p>

## Limitations of the ICADTS list

It is not the objective of the ICADTS Working Group to review all available literature again in assigning categories for medicinal drugs and thereby duplicating the work that has been done in Belgium, Spain and France, respectively in 1999, 2002 and 2005.

An updated review will be done in the near future within the Sixth Framework Programme of the European Union as an Integrated Project entitled DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) that is aiming to start in September 2006.

Furthermore, the list will only contain medicinal drugs which are on the market in either, Belgium, Spain or France and therefore will not cover all drugs within a therapeutic class.

Another limitation is the lack of information in the categories on the various dosages that are used for the different medicinal drugs. **As a general rule the categories are assigned to the drug in the normal therapeutic dosage given to an adult person for the main indication of the drug.** If higher dosages are taken one should consider the drug to be categorized as being one category higher if not yet assigned to the highest category.

## General prescribing and dispensing guidelines

Although it is the objective of the ICADTS list to support the physician and pharmacists in selecting the safest alternatives within each therapeutic class, if available, specific attention should be given to general prescribing and dispensing guidelines:

Prescribing Guidelines	Dispensing Guidelines
1. Realize that the use of some psychoactive drugs has been associated with an increased risk of causing an injurious accident and that patients should receive this information.	1. Discuss with prescribing physicians what patient information (written and oral) should be provided at the first delivery of a particular impairing drug
2. Consider an alternative in the light of experimental research showing large differences between the effects on driving performance of various drugs within the same therapeutic class .	2. Inform the prescribing physician that alternative drugs exist in case a drug in class II or III has been prescribed, and inform the patient.
3. Start with the lowest doses of psychoactive medical drugs and whenever possible avoid multiple dosing over the day.	3. Advise the physician to prescribe the lowest effective dose of a particular psychoactive medicinal drug and to avoid multiple dosing over the day. Inform the patient.
4. Do not reflexively "double the dose" if patients fail to respond to psychoactive medication.	4. Advise the physician to try another drug if the patient reports a lack of efficacy after beginning of treatment and inform the patient. If higher doses are needed advise the patient to use the largest part before sleep (if compatible with the therapeutic regimen).
5. Avoid prescribing different psychoactive drugs in combination.	5. Explain to the patient that poly-therapy with psychoactive drugs is always an experiment with the patient's safety and avoid to driving if treatment can not be adjusted.
6. Do not rely solely upon the manufacturers' advice for counselling patients about the effects of drug upon driving.	6. Explain to the patient why warnings provided by the manufacturer about their drug's effects on driving are vague, illogical and sometimes misleading.
7. Advise patients concerning the ways they can minimize the risk of causing a traffic accident if it is impossible to avoid prescribing an obviously impairing drug or one with unknown impairing potential (see next Table).	7. Advise the patient the ways they can minimize the risk of causing a traffic accident if they have to use a drug with an impairing potential (see next Table).
8. Monitor the patient's driving experience with the drug.	8. Monitor the patient's driving experience with the drug (e.g. at the first refill) and report back to the physician or ask the patient to inform the physician.

For some frequently used drug classes more specific information can be provided to guide the physician and pharmacist in prescribing and dispensing these psychotropic drugs. These are just given as examples (source: ICADTS Working Group report, 2001).

Drug class	Drugs with little or no impairment	Risk factors	Prescribing information	Dispensing Information
<b>Anti-histamines</b>	Ebastine 20 mg OD Fexofenadine 60 mg b.d.s. or 120 mg/180 mg OD Loratidine 10 mg OD	Liver and/or renal dysfunction		<p>1. Avoid alcohol while taking this drug</p> <p>If drugs with little or no impairment can NOT be dispensed and/or at the beginning of treatment (also with least impairing one) focus on:</p> <p>2. Recognize signs of impaired driving performance (stop for rest if any occur):</p> <ul style="list-style-type: none"> <li>• Blurred vision</li> <li>• Difficulty in concentrating or staying awake</li> <li>• Unusual surprise by ordinary traffic events</li> <li>• Not being able to remember how exactly you came at destination</li> <li>• Difficulty in holding steady course in traffic lane</li> </ul>
<b>Anti-depressants</b>	Fluoxetine 20 mg OD Moclobemide 200 mg b.d.s. Paroxetine 20 mg OD  Venlafaxine 75-150 mg q.d. (an SNRI effective in more than 80% of patients with generalized anxiety disorders)	No specific risk factors known  No specific risk factors known	<p>Avoid combined use of fluoxetine and nonselective MAOIs, tryptophan, selegiline, terfenadine (adverse drug interactions)</p> <p>Avoid combined use of moclobemide and dextromethorphan, (tricyclic) antidepressants, (pseudo)ephedrine (adverse drug interactions)</p> <p>Avoid combined use of paroxetine and nonselective MAOIs, (dex)fenfluramine and selegiline (adverse drug interactions)</p> <p>Avoid combined use of venlafaxine and nonselective MAOIs (adverse drug interactions)</p>	<p>1. Avoid alcohol while taking this drug.</p> <p>If drugs with little or no impairment can NOT be dispensed and/or at the beginning of treatment (also with least impairing one) focus on:</p> <p>2. Recognize signs of impaired driving performance (stop for rest if any occur):</p> <ul style="list-style-type: none"> <li>• Blurred vision</li> <li>• Difficulty in concentrating or staying awake</li> <li>• Unusual surprise by ordinary traffic events</li> <li>• Not being able to remember how exactly you came at destination</li> <li>• Difficulty in holding steady course in traffic lane</li> </ul>

Note: The sequence in which the safer alternatives are mentioned is based on alphabetic order and do not express any therapeutic preferences

Drug class	Drugs with little or no impairment	Risk factors	Prescribing information	Dispensing Information
<b>Hypnotics</b>	> 10 h post dosing; taken at night: Lormetazepam 1 mg Temazepam 10 mg Zolpidem 10 mg	Combination with other psychoactive drugs  Liver and/or renal dysfunction (elderly patients: half the normal dose)	Avoid prescribing for longer than 2-4 weeks	1. Avoid alcohol while taking this drug  If drugs with little or no impairment can NOT be dispensed and/or at the beginning of treatment (also with least impairing one) focus on:  2. Recognize signs of impaired driving performance (stop for rest if any occur): <ul style="list-style-type: none"> <li>• Blurred vision</li> <li>• Difficulty in concentrating or staying awake</li> <li>• Unusual surprise by ordinary traffic events</li> <li>• Not being able to remember how exactly you came at destination</li> <li>• Difficulty in holding steady course in traffic lane</li> </ul> 3. Avoid taking longer than 2-4 weeks and more than one at night
<b>Tranquillizers</b>	Buspirone 10 mg b.d.s.  SSRI's are effective in more than 60% of patients with generalized anxiety disorders : Fluoxetine 20 mg OD Paroxetine 20 mg OD  Venlafaxine 75-150 mg q.d. (an SNRI effective in more than 80% of patients with generalized anxiety disorders)	No specific risk factors known  No specific risk factors known  No specific risk factors known	Avoid combination with selective serotonin reuptake inhibitors (SSRIs) because of reduced therapeutic effect  Consider combination for 1 week with oxazepam 10 mg t.d.s. if therapeutic response seems to be inadequate (forbid driving during the first week)  Avoid combined use of fluoxetine and nonselective MAOIs, tryptophan, selegiline, terfenadine (adverse drug interactions)  Avoid combined use of paroxetine and nonselective MAOIs, (dex)fenfluramine and selegiline (adverse drug interactions)  Avoid combined use of venlafaxine and nonselective MAOIs (adverse drug interactions)	1. Avoid alcohol while taking this drug  If drugs with little or no impairment can NOT be dispensed and/or at the beginning of treatment (also with least impairing one) focus on:  2. Recognize signs of impaired driving performance (stop for rest if any occur): <ul style="list-style-type: none"> <li>• Blurred vision</li> <li>• Difficulty in concentrating or staying awake</li> <li>• Unusual surprise by ordinary traffic events</li> <li>• Not being able to remember how exactly you came at destination</li> <li>• Difficulty in holding steady course in traffic lane</li> </ul>

Note: The sequence in which the safer alternatives are mentioned is based on alphabetic order and do not express any therapeutic preferences

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