



## Could it be your medicine?

Common symptoms that could be caused by adverse drug reactions

**abstract** ■ **Objective:** to offer the physician a list of common symptoms that derive from adverse drug reactions and a relationship between common drugs or classes of drugs that are most frequently implicated. **Material and methods:** clinical physicians, pharmacists and physicians working for the Department of Information Systems and Clinical Management were asked to identify the most common problems encountered in their daily practice and in which medications could be at the root of these effects. This issue was also presented to an internet forum on Family Medicine and Primary Care. A bibliographical search was carried out in UpToDate® and MEDLINE updated on April 2011. Only review articles were included. We also searched the TRIP database and BOT Plus database which registers information on the Summary of Product Characteristics reports. **Results and conclusions:** we provide a list of common symptoms that can derive from adverse reactions to drugs, and a relationship between the drugs or classes of drugs most frequently implicated. The list could represent a helpful tool for the e-prescribing software of the electronic medical record. **Key words:** adverse reactions, drug induced symptoms, pharmacovigilance.

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### Clinical case

In July 2009, a 78 year old woman presented at the consultancy with a 4-day history of sudden cosmia. She explained that she went to bed feeling fine and in the morning she woke up with a sense of bad odour around. She cleaned up the house but the smell persisted.

### Relevant past history

Hipothyroidism. Spondyloarthritis. Episodes of sciatic pain due to L4-L5 segment affectation. Spastic colon. Hyperlipidemia.

### Current treatment

Levothyroxine 100 mg daily  
 Simvastatin 10 mg daily  
 Ibandronate 150 mg monthly  
 Calcium+vitamin D: 1000 mg-880 IU b.i.d.  
 Lansoprazole: 30 mg daily  
 Ibuprofen in case of pain  
 Pregabalin 75 mg daily

### Clinical evolution of the case

A general and neurological examination was performed with no findings. Nasal corticoid and antimicrobial treatment was initiated with a suspicion of acute sinusitis, and the patient was referred to a neurologist and an otolaryngologist to rule out cortex, hypophysitis or sinus affectation.

The patient was examined by the otolaryngologist who recommended clonazepam and intramuscular betametasone. She presented poor tolerance to clonazepam and it was discontinued. A sinus CT scan was carried out which was normal. After evaluation by a neurologist, where an electroencephalogram was performed which was normal, a cranial MRI was carried out which also turned out to be normal.

While completing the study, the patient discontinued treatment with pregabalin on her own, as it was the most recent novel therapy she had started. Symptoms disappeared once pregabalin was stopped. To date she remains asymptomatic.

*The drug information leaflet of pregabalin indicates numerous undesirable effects on the nervous system, among them ageusia. The alterations in taste and in smell are related and can be produced by different drugs from the class of antiepileptic<sup>1</sup>. It is important to notify the Center for Pharmacovigilance to enable a better comprehension of the safety profile of all medications.*

### The problem

An important part of the population is under chronic treatments. We should not forget that when prescribing a drug to achieve clinical benefit, the treatment also affects the functioning of patient's organism. It should therefore not be surprising that adverse reactions represent an important health problem.

Behind the undesirable effects, which are the objective of warnings issued by regulating bodies and the characteristic reactions that appear in pharmacological texts, there lies the danger of complications that produce symptoms that are frequently unclearly defined and can cause confusion with the underlying disease or simulate any other disease. These reactions deteriorate the patients quality of life, make diagnosis and management of the patient's diseases difficult, and can lead to what is known as "prescription cascade" that is, treatment of the undesirable effect of a drug by another drug.

To attribute the cause of a symptom to a drug can be difficult and often is not done until suspension of the drug produces improvement in health. It should be taken into account that any symptom can be caused by medications even those symptoms which have yet not been documented as adverse reactions.

Special attention should be given to new medications because their safety profiles are often not known when they become available on the market. Medications are often commercialised with identified adverse effects, but it is also admitted that there is still information lacking. This is reflected by the fact that new medications are accompanied by a risk management plan (that includes known and potential risks). To mark out new drugs, and therefore to indicate the existence of less information on their safety profile, in Spain it is compulsory to include in all advertising material for health professionals the yellow pictogram ('▲'), for a period of 5 years from the time of the drug's authorization.

Summaries of Product Characteristics contain a lot of information on adverse reactions, but do not always respond to the needs of the clinician. The data may derive from clinical trials carried out in controlled conditions, in selected populations and may be of short duration.

Therefore, the real frequency of adverse reactions remains unknown in common daily conditions of use. Moreover, it is necessary to review all the drug information lists of all the medication a patient may be taking which would take considerable time and effort.

Besides the symptoms caused by medications, consideration should be given to those effects that result from the withdrawal of drugs, especially if withdrawal is sudden (table 2). Good communication between doctors and patients is essential to tackle the problem. If we want to detect drug-related symptoms, it is necessary to ask and **listen actively** to our patients.

### Our objective

The aim of this article is to provide the physician with a list of the most common symptoms that could be caused by adverse reactions, and a relationship between the drugs or classes of drugs most frequently implicated.

### Methodology

The first difficulty encountered was to make a selection of symptoms. Practically any symptom that a patient could present can be caused by medications. To address the problem, practising physicians, pharmacists, and physicians from the Department of Information Systems and Clinical

Management were asked to identify the problems they most frequently encountered in their daily practice and which could be caused by medication. The issue was also presented to an internet forum on Family Medicine and Primary Care (MED-FAM-APS).

During a meeting of the Editorial Board of the Drug & Therapeutics Bulletin of Navarre, brainstorming techniques were applied to propose symptoms. Once completed, all the information recollected was re-evaluated to prioritize those symptoms to be studied.

Another problem was the enormous amount of information to be managed. Our objective was to focus on commonly used drugs in primary care and the most common and validated reactions. Medications restricted to hospital use including anti-neoplastic agents or HIV antiviral therapy were excluded.

A bibliographical search was carried out in the electronic book UpToDate® and MEDLINE using the following strategy: "*problem*/chemically induced"[Mesh] or ("*problem*" [Mesh] AND "Diagnosis, Differential" [Mesh]." Only review articles were selected. A search was also made in the TRIP database and the BOT Plus<sup>2</sup> database which collects information on the Summary of Product Characteristics of all medications. As our selection was reviews, recently marketed drugs were not included, and so the Summary Product Characteristics reports of the most commonly employed medications marketed over the last 5 years were also checked.

### Conclusion

This article offers the physician a list of the common symptoms that could cause adverse reactions to drugs, and a relationship between drugs or classes of drugs that are most frequently implicated. The result is only a starting point which can be completed and updated, and even included as a helpful tool for the e-prescribing software of the electronic medical record.

Physicians require better information on drug safety in real conditions of use. This can only come through spontaneous notifications of the suspicion of adverse reactions (Yellow Card Scheme) and more and better pharmacoepidemiological studies. The adequate codification of symptoms and treatments in the electronic medical record is essential to carry out such studies.

**Warning:** as explained earlier we have focussed on the most common problems of the most frequently employed medications. We do not present a comprehensive list of medications that could produce an undesirable effect. Moreover, the sources do not always coincide when attributing an adverse reaction to a class of drugs. There are much more relations between adverse reactions and drugs than those presented here. If there is any suspicion of an adverse effect then the physician should consult the Summary of Product Characteristics or consult the Pharmacovigilance Centre or the Drug Information Centre.

### Acknowledgements

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**Table 1.** Common symptoms (ordered according to ICPC or ICD-9 codes) and the medication implicated (ordered according to therapeutic group ATC).

Symptom	(ICPC, ICD-9)*	Medication	Observations
<b>Asthenia</b> <sup>3,4</sup>	A04 780.7	Dronedarone Ranolazin Antihypertensive agents: betablockers most frequently implicated Opioids Benzodiazepines Antidepressants H <sub>1</sub> Antihistamine agents	
<b>Diarrhoea</b> <sup>5,6,7</sup>	D11 558.9	Antiacids containing magnesium H <sub>2</sub> antihistamine agents Misoprostol Proton pump inhibitors Metformin Acarbose, miglitol Exenatide, liraglutide Cilostazole Digoxin Antiarrhythmic agents Aliskiren Nicotinic acid/laropiprant Ezetimibe Antibiotics NSAIDs Strontium ranelate Carbamazepine SSRI, duloxetine, agomelatine Teophiline Roflumilast	

Symptom	(ICPC, ICD-9)*	Medication	Observations
<b>Constipation</b> <sup>5-7</sup>	D12 564.0	Antiacids containing aluminium H <sub>2</sub> Antihistamine agents Proton pump inhibitors Sucralfate Laxatives (chronic use) Calcium supplements Iron supplements Amiodarone Ranolazin Diuretic agents Betablockers Calcium channel blockers Cholestiramine, colestipol Oral contraceptive agents Urinary antispasmodic agents NSAIDs Bisphosphonates	
		Opioids	Prescription should be accompanied by preventive measures, including laxatives
		Antipsychotics Anticholinergic agents for Parkinson disease Lithium Tricyclic antidepressants, duloxetine, venlafaxin H <sub>1</sub> Antihistamine agents	
<b>Vertigo</b> <sup>8</sup> Considered of vestibular origin	H82 386	Loop diuretics Amiodarone Aminoglycosides NSAIDs Acetylsalicylic acid	
<b>Muscle cramps</b> <sup>9</sup>	L14, L19 728.2 729.9 729.8	Diuretics Dihydropyridine calcium channel blockers Statins Nicotinic acid/laropiprant Raloxifene, bazedoxifene Penicilamine Antipsychotics: phenothiazines Beta 2 adrenergic agonists	
<b>Muscular pain</b> <sup>10,11</sup>	L18 729.1	Statins Fibrates	Evaluate risk of rhabdomyolysis. Precaution with interactions.
		Corticoids Quinolones Colchicine Bisphosphonates Quinine, chloroquin	
<b>Cefalea</b> <sup>12</sup>	N01 784.0		

Symptom	(ICPC, ICD-9)*	Medication	Observations
<b>Due to acute exposure</b>		Cilostazole Nitroglicerine Ivabradine, ranolazine Betablockers Calcium channel blockers Nicotinic acid/laropiprant Sildenafil, vardenafil NSAIDs Theophylline Roflumilast	
<b>Due to abuse of medication</b>		NSAIDs Opioids Paracetamol Ergotic agents Triptans	
<b>Due to chronic use</b>		Retinoid agents Oestrogens Corticoids Thyroid hormone Indomethacin Lithium	Possible craneal hypertension
<b>Acute dystonia<sup>13</sup></b>	N08 781.0	Metoclopramide, domperidone Antipsychotics H <sub>1</sub> Antihistamine agents	(see table 4)
<b>Tremor<sup>14</sup></b>	N08, N99 333.1	Metoclopramide	Withdraw. Employ domperidone. Watch for signs of parkinsonism
		Procainamide	
		Amiodarone	Consider hyperthyroidism, reduce dose to 200 mg daily. Consider a betablocker
		Valproate acid	Reduce dose. Change to another antiepileptic drug
		Antipsychotics	Watch for signs of parkinsonism (see table 4). Withdraw. Change to another of lower risk
		Lithium	Monitor concentrations
		Antidepressants: tricyclic, SSRI, duloxetine, venlafaxin, bupropion	Can improve over time. Precaution due to possible serotonergic syndrome (see table 3)
		Adrenergic agonists: efedrine, phenylpropanolamine, pseudoephedrine Beta 2 adrenergic agonists.	Can improve over time
		Theophylline Roflumilast	

Symptom	(ICPC, ICD-9)*	Medication	Observations
<b>Alterations in taste (ageusia) or smell<sup>1,15</sup></b>	N16 781.1	Clorhexidine Propaphenone Amiodarone, dronedarone Nitroglycerin Diuretics: acetazolamide, amyloride, hydrochlorothiazide, spironolactone Calcium channel blockers ACE inhibitor and ARBs Statins Antifungal agents: terbinafine, griseofulvin Corticoids Thyroid therapy: levothyroxine, carbimazole, tiamazole Antimicrobials: ampicillin, azithromycin, ciprofloxacin, clarithromycin, etambutol, metronidazole, ofloxacin, sulphamethoxazole, ticarcillin, tetracycline Antiviral agents: aciclovir, amantadine, interferon, osetalmivir Penicillamine Colchicine Triptans Antiepileptic agents Antiparkinson agents Lithium Sedatives and hipnotics: alprazolam, fluracepam, buspirone, zolpidem Antidepressants: tricyclic, SSRI, duloxetine, venlafaxine, bupropion H <sub>1</sub> Antihistamine agents	
<b>Dizziness/unstability<sup>8,16</sup></b>	N17 780.4	Cilostazole Ivabradin, ranolazine Antihypertensive agents Nicotinic agents/laropiprant Alpha blockers NSAIDs Antiepileptic agents Benzodiazepines Antidepressants Antivertiginous agents (chronic use)	
<b>Anxiety/agitation<sup>2,17</sup></b>	P01, P04, P74 300.0	Opioids	
		Triptans	Precaution with possible serotonergic syndrome (see table 3)
		Antiparkinson agents	
		Antipsychotics	(see table 4)
		Benzodiazepines	
		Antidepressants: tricyclics, SSRI, duloxetine, venlafaxin, reboxetine, bupropion	Precaution with possible serotonergic syndrome (see table 3)
		Methylphenidate, atomoxetine	
		Adrenergic agonist: ephedrine, phenylpropanolamine, pseudoephedrine	
		Roflumilast	

Symptom	(ICPC, ICD-9)*	Medication	Observations
<b>Insomnia</b> <sup>18</sup>	P06 307.4, 780.5	Betablockers Calcium channel blockers Corticoids Antidepressants: tricyclics, SSRI, duloxetine, venlafaxine, bupropion, agomelatine Methylphenidate, atomoxetine Adrenergic agonists: ephedrine, phenylpropanolamine, pseudoephedrine Beta 2 adrenergic agonists Theophylline	
<b>Delirium</b> <sup>19,20</sup>	P29 290.3 293.0 298.2	H <sub>2</sub> Antihistamine agents	
		Digoxin	
		Propaphenone	
		Betablockers	
		Urinary antispasmodic agents	Anticholinergic effects are an important cause of confusion in elderly patients
		Corticoids Betalactamics Quinolones NSAIDs Opioids Antiepileptic agents Antiparkinson agents Antipsychotic agents	Anticholinergic effects are an important cause of confusion in elderly patients
		Benzodiazepines Tricyclic antidepressants	Anticholinergic effects are an important cause of confusion in elderly patients
		SSRI	Precaution with possible serotonergic syndrome (see table 3)
	First generation H <sub>1</sub> antihistamine agents	Anticholinergic effects are an important cause of confusion in elderly patients	
<b>Hallucinations</b> <sup>21,22</sup>	P29 306.7	H <sub>2</sub> antihistamine agents Digoxin Betablockers Corticoids Clarithromycin Opioids Dopaminergic antiparkinson agonists Benzodiazepines Antidepressants Methylphenidate Adrenergic agonist: ephedrine, phenylpropanolamine, pseudoephedrine	



Symptom	(ICPC, ICD-9)*	Medication	Observations
<b>Mania</b> <sup>23,24</sup>	P73 296.0 296.1	Corticoids Dopaminergic antiparkinson agents Antidepressants Methylphenidate, atomoxetine	
<b>Distimia</b> <sup>23,25,26</sup>	P76 300.4	Digoxin Betablockers ACE inhibitors, ARBs Contraceptives Corticoids Interferons NSAIDs Antiepileptic agents Benzodiazepines Calcium channel blockers: flunarizine Roflumilast	
<b>Pruritus</b> <sup>27</sup> These are not considered hypersensitivity reactions as any medication can produce it	S02 698.8 698.9	Sulphonylureas Betablockers Calcium channel blockers ACE inhibitors, ARBs Statins Nicotinic acid/laropiprant Sexual hormones Betalactamics Macrolids Quinolones Tamoxifen NSAIDs Alopurinol Opioids Antiepileptic agents Antipsychotic agents Antidepressants Antimalarial agents	Can be due to cholestasis

NSAIDs: Non steroidal anti-inflammatory drugs.  
ACE: Angiotensin converting enzyme.  
ARBs: Angiotensin II receptor blockers.  
SSRI: Selective Serotonin Reuptake Inhibitors.

(\*) These include ICPC and ICD-9 codes of diseases that can be related to an adverse reaction but may not necessarily be the correct code of the problem.

**Table 2.** Problems related with the abrupt withdrawal of commonly used drugs in primary care<sup>2,28</sup>.

MEDICATION	PROBLEM
Proton pump inhibitors	Rebound acid hypersecretion
Antihypertensive drugs <sup>29</sup>	Rebound hypertension Symptoms of sympathetic hyperactivity
Betablockers	Coronary ischemia
Corticoids <sup>30</sup>	Adrenal insufficiency: fatigue, anorexia, weight loss, gastrointestinal disorders, dizziness, hypotension, muscle pain
Opioids	Abstinence syndrome.
Gabapentin, pregabalin	Convulsions, anxiety, insomnia, pain, nausea, diarrhoea, flu-like syndrome, nervousness, depression, sweating and dizziness
Benzodiazepines	Abstinence syndrome Relapse
Antidepressants <sup>31</sup>	Flu like syndrome, insomnia, nausea, dizziness, anxiety, agitation sensory disorders, tremor
Methyphenidate	Depression
Antipsychotics	Relapse Cholinergic rebound: nausea, anxiety, insomnia, agitation, dyskinesia

**Table 3.** Serotonergic syndrome<sup>13,32</sup>.

SYMPTOMS	MAJOR	MINOR
<b>Mental</b>	Confusion Hypomania Coma or altered level of conscious	Agitation, nervousness Insomnia
<b>Autonomous</b>	Fever Hyperhidrosis	Tachycardia Tachypnea, dispnoea Diarrhoea Hypotension or hypertension
<b>Neurological</b>	Rigidity Myoclonus Tremor Hyperreflexia	Acathisia Altered coordination Mydriasis

**Implicated medications**

Antidepressants: SSRI, tricyclics, MAO inhibitor, bupropion, trazodone, nefazodone, venlafaxine, duloxetine, hypericum.

Triptans.

Opioids: fentanyl, tramadol, pentazocine, meperidine, dextrometorphan.

Selegiline, sibutramine, lithium, ondansetron, granisetron.

*Frequently this syndrome is caused by the interaction of various of these drugs.*

**Table 4.** Main extrapyramidal reactions related to antipsychotic agents<sup>2,13</sup>.

YATROGENIC EPISODE	CHARACTERISTICS
Parkinsonism	Rigidity, bradikinesia, tremor, characteristic gait.
Acute dystonia	Muscle spasm in tongue, face, neck and back. More common in young patients.
Akathisia	Motor agitation, without psychological symptoms
Late dyskinesia	Facial movements of mastication and sucking, involuntary movements in the legs, trunk dystonia. More common in elderly patients.

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