

MARK S. KOSINS MD & Staff

DIPLOMAT-AMERICAN BOARD OF PSYCHIATRY AND NEUROLOGY

647 CAMINO DE LOS MARES #226
SAN CLEMENTE, CALIFORNIA 92673

(949) 489-9898=phone

(949) 489-2569=fax

To my patients: Regarding the use of off label medications. Please ask questions.

Medications are developed and approved by the food and drug administration (FDA). They are given specific indications for specific uses based upon very detailed and expensive testing. We want to make sure they are safe and work. Often times we have found that medications are effective when used in situations called off-label. This means they are not FDA approved but have been shown to be helpful and much literature exists to support the use of medicines off label. For example there is no medicine indicated for the treatment of Bipolar Disorder in Children or behavioral disruptive conditions or autistic spectrum disorders. Yet we must treat these conditions.

In addition, I use caution to use combinations or supplements and or medications that are often helpful and result in increased effectiveness for a multitude of conditions such as unusual pain disorders, ADHD, ADD, Bi-Polar Disorder, Anxiety Disorder, Panic Attacks, oppositional defiant disorder, Bi-Polar Spectrum Disorder, Depression, Dysthymia, and others like behavioral loss of control, irritability, temper, rages, anger, impulsivity, lack of attention, low frustration tolerance, etc. Furthermore, combinations of medications are often better than a high dose of one medication.

Though side effects are common with all medications, it is important to distinguish between side effects that are inconvenient and those that are dangerous. Inconvenient would be a slight bit of nausea or transient trouble falling asleep. Dangerous side effects can cause irreversible damage. So I try to be as careful with you as I would with my own family even if the chances of a problem are 1 in 1000 or 100,000 or 1,000,000.

If a blood test is helpful, I will give you a prescription for one. If you have any unusual symptoms that are very mild, they will most likely go away. If you have any that concern you an e-mail is helpful for non urgent issues, but for urgent issues please CALL. I try to be very available and return my phone calls daily.....please don't call it an emergency unless it is one. If ever in doubt and you can't reach me or my associate, go directly to an emergency room.

The medications and supplements I use help a person's brain chemistry function more normally. I never have the goal of turning someone into a zombie or making them zoned out.

Examples:

1. Mood Stabilizers...originally used for epilepsy. Many are approved for Bipolar disorder and migraine. Most of my patients never get any serious side effects and even the inconvenient ones are reduced because we start with a low dose and increase very slowly. Examples are:

- a. Depakote...requires blood tests to check blood level, blood and liver function.

- b. Tegretol...requires blood tests to check blood level, blood and liver function.
 - c. Gabitril...no tests required.
 - d. Neurontin and Lyrica...no tests required
 - e. Topamax...no tests ...rare kidney stones..rare increased eye pressure.
 - f. Lamictal.....can rarely cause a rash.....notify me at once and stop the medicine.
 - g. Lithium..... Requires blood test for thyroid, kidney function and blood level of lithium...
 - h. Zonegran ...no tests
 - i. Trileptal ... a rare rash
 - j. And others. Although it is very uncommon, if you get a rash while taking any of the above medicines...stop it at once and call me.
2. **Atypical Anti-psychotic Medications:** These are used for severe psychiatric disorders in high doses. They have been shown to be effective in low doses in combination or alone for many of the disorders I have noted above. These medications include:
- a. Risperdal...rarely increases prolactin...we can test for this
 - b. Zyprexa....most likely to cause weight gain.
 - c. Seroquel....can be used at times in low doses for sleep
 - d. Geodon...may require a electrocardiogram---uncommon
 - e. Abilify...rarely can cause muscle stiffness o
 - f. Clozapine...requires frequent blood monitoring
Thorazine (chlorpromazine), Mellaril, Stelazine, Navane and others are “typical” anti-psychotic medications we sometimes use for off label use.
3. Medications usually used for blood pressure control:
- a. Clonidine (catapress) is often useful for impulse control, pain and tic disorders.
 - b. Tenex...often used for impulse control
 - c. Beta Blockers such as inderol, propranolol, atenolol, viskin, zebeta and others for headaches and for impulse control and rapid heart beat or tremor.
4. We may also use medicines for sleep like Trazodone (desyrel), or muscle pain (soma, or robaxin), and various other medicine for a detox from various drugs or alcohol. Or we may use Xyrem (a medicine for narcolepsy) to help with the pain for Fibromyalgia.
5. We may also use medication for Attention Deficit Disorder and Oppositional Defiant Disorder that include a combination of medications such as a psycho stimulant, a mood stabilizer or an SSRI/SNRI like Prozac, Paxil, Effexor, Celexa, Zoloft and other medications that are appropriate. ALWAYS LET US KNOW WHAT HERBS OR OVER THE COUNTER MEDICATIONS OR VITAMINS YOU USE.
- a. The FDA notes that stimulants may have a slight increased incidence of cardiac (heart) side effects in patients that have a structural defect, heart irregularities, hypertension that is not controlled and frequent bouts of dizziness,

fainting, chest pain, rapid heart beat or history of heart attack. Please let me know if you know of any issues related to this. Let us know if there is any history of heart problems in you or your first degree family relatives. In this instance an EKG or physical exam from your primary care doctor or pediatrician may be indicated.

b. The FDA also notes that very rarely Psychosis, Aggression, and severe behavioral disorders can occur with stimulants. If any this should happen while you are first taking stimulants or any time, please let us know at once.

c. Finally there is the issue of growth. In a 3 year study it was noted that on average children lost 5 pounds compared to children not on stimulants and grew about $\frac{3}{4}$ of an inch less. Studies are underway to see if this changes their total height as an adult.

6. As it relates to taking anti depressants in children and adolescents; Rarely there is an increase in suicidal thinking in children and adolescents who have been started on anti depressant. Of course they did not feel well in the first place, and it is thought that the increase in this thinking is due to the activating effect of the medications (especially in the first weeks on the medication). With this in mind, it is important to monitor children more closely when first starting these medications. If there is any doubt please contact us at once.

There are other examples and I will explain if I/we...use any others. This list is not inclusive and I may use unusual combinations of medications to achieve goals which we will discuss. I will always be happy to explain what I am doing and why. Just ask.

INFORMED CONSENT

I have been told that medications as described above may be used off label. I have had an opportunity to ask questions and have been told about common side effects. Furthermore, I know how to reach the doctor in an emergency.

Date: _____ Patient Signature: _____ Clinician _____

