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Examples of Off-Label Medication Use for Mental Health Conditions

Amitriptyline	<ul style="list-style-type: none"> • Insomnia • Posttraumatic stress disorder (PTSD)
Clonidine	<ul style="list-style-type: none"> • Smoking cessation • Excessive saliva caused by clozapine
Gabapentin	<ul style="list-style-type: none"> • Alcohol dependence • Social anxiety
Prazosin	<ul style="list-style-type: none"> • Posttraumatic stress disorder (PTSD) nightmares
Topiramate	<ul style="list-style-type: none"> • Alcohol dependence • Weight gain caused by antipsychotic medication • Binge eating disorder • Bulimia
Trazodone	<ul style="list-style-type: none"> • Insomnia

What are FDA-approved medications?

The United States Food & Drug Administration (FDA) is responsible for regulating both prescription and non-prescription medications. One of their roles in regulation is to ensure that medications are safe and effective. This is done through the FDA approval process.

What is off-label medication use?

This means the medication is used in a way that is not stated in the FDA labeling. Medications may be used off-label for several reasons such as:

- For a disease or condition that it is not approved to treat. For example, using some antidepressant medications to treat nerve pain.
- At a different dose than approved. For example, a lower or higher dose of the medication may be used for some patients.
- In a different dosage form than approved. For example, a medication that is approved for use with an oral tablet but prescribed with an oral solution.¹

Why are medications used off-label?

Off-label use of medications is common. Although common, many patients may not know that a medication is prescribed off-label. So why are medications used off-label?

One reason may be that the FDA approval process is expensive and time-consuming. If the company would like to add an indication to a medication, an additional application is required. For this reason, a medication may still be helpful for off-label use even if it is not approved by the FDA. Off-label use of medications can be particularly useful for patients who have tried all other

medications for a disease. Another reason a medication may be prescribed off-label is because there might not be an approved drug to treat a disease. One example is cancer medication. Often a cancer medication may be approved to treat one type of cancer but is used off-label to treat other types of cancers. Although a medication is not approved for a condition, it may have been studied for its benefits in that condition.^{1,2}

Approximately 20% of prescriptions are for an off-label use.

FDA Approval Process

Drug company submits a medication to the FDA

Drug company shows proof that the medication is safe and effective

FDA decides if they will approve or deny the medication

How does a doctor decide to use a medication off-label?

Once a medication is approved for one use, doctors can decide whether it is right for other uses. Several factors are considered when a health care provider decides to prescribe a medication. This includes deciding whether the medication is safe and effective for a specific patient.^{2,3}

Is it safe to use a medication off-label?

In most cases, taking a medication for off-label use is safe. Drug companies are required to prove that a medication is safe for people to use. They just don't need to prove the drug works for treating an off-label condition. Sometimes a medication could help with symptoms of conditions that it was not approved for. There are many off-label uses that most doctors agree are safe and effective.⁴

Remember!

- *Off-label use means that an approved drug is used in a way that is not approved by the FDA.*
- *This may include:*
 - *use of a medication for an unapproved indication or disease*
 - *use of a medication at an unapproved dose*
 - *use of a medication in an unapproved dosage form*
- *Consider asking your doctor about off-label use of medications that you are prescribed.*



Go online to learn more about off-label usage of medications, and to view the references for this toolkit.

aapp.org/366992

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