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Oxybates: 1 Molecule, 3 Formulations – Safety

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

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Dr. Thorpy:

This is CME on ReachMD, and I'm Dr. Michael Thorpy. Here with me today is Dr. Clete Kushida.

We've talked about the 3 different agents that are available for the treatment of narcolepsy that all contain oxybate. Two of them are twice-nightly formulations, and one is a once-nightly formulation. And we heard about the efficacies, which is showing that they're efficacious for cataplexy and excessive daytime sleepiness, and also improve nighttime sleep. But how about the safety, Clete? Can you tell us a bit about the safety information from the clinical trial data?

Dr. Kushida:

Sure, Michael. So one of the more common types of adverse reactions that have been noticed in adults with greater than or equal to 5% were things like nausea, headache, dizziness, also vomiting, somnolence, bed-wetting, and tremors. So these are some typical adverse reactions that might occur in low frequency in these patients when they're compared, at least twice the incidence with placebo.

Things that we always kind of are concerned with these class of medications are things like CNS depression. So we always want to make sure that when these medications are taken, it's not coupled with another central nervous system depressant. And then, you know, sleepiness in the daytime can be a carryover effect. So we would always want to counsel patients against hazardous activities like if they have to go on a long drive or where, you know, they have to be very mentally alert at their job or other type of positions where they might be in hazardous situations.

So the sleepiness is an issue, and then another thing that we also keep in the back of the mind is depression. So in some patients, there have been depression as well as some suicidality, so that's something to keep in mind. And then sleepwalking can occur. It's not that frequent, but it can occur in certain patients. And lastly – and we'll be talking about this later – is that given the sodium content, it's not really a cause of concern, but it is something to look at in specific classes of patients.

Dr. Thorpy:

Thank you, Clete. So these 3 medications have very similar symptoms or adverse effects, don't they? And so overall, oxybate is very safe when taken in the prescribed manner. In general, the side effects tend to occur when you initiate the treatment, in the first couple of weeks of treatment, and the one that tends to come on a bit later seems to be that enuresis, and that often increases with the highest dose. But we have to bear in mind these clinical trials. And in the clinical trials, they weren't able to advise the patients about other measures to take to reduce that enuresis. For example, what we clinically do is to ask patients to reduce the amount of fluid intake before going to bed and also make sure that they go to the bathroom before they take the medicine at night, and that tends to lessen the enuresis that was seen in the clinical studies.

Well, this has been a great bite-sized discussion. Unfortunately, our time is up. Thank you for listening.

Announcer:

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