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### Cardiovascular Effects of Oxybate: A 20-Year Safety Record

#### 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.

Now, oxybates are the primary pharmacological agent that's used to treat the symptoms of narcolepsy, the excessive daytime sleepiness, the cataplexy, and the disturbed nocturnal sleep. And there have been questions that have arisen about the sodium intake with sodium oxybate. Two of the formulations do have sodium with them, and it's quite a high amount of sodium, up to 1600 mg with the highest dose. And the third formulation is a formulation that has low sodium content.

So, Clete, can you tell us a little bit about the sodium content of the oxybates? And also, what is the potential for cardiovascular risk in patients with narcolepsy?

#### Dr. Kushida:

Absolutely, Michael. So interestingly, researchers have been studying sodium oxybate for narcolepsy about 20 years ago, and in the course of looking at this research, what we found was there's about 9 studies and 2 publications that have focused on post-marketing surveillance of sodium oxybate. And when you look at these data, it is quite striking that for sodium oxybate, it really is not directly linked in adults to cardiovascular risk. So for most people, the sodium in sodium oxybate should not be a cause of concern for those that are taking it for narcolepsy in terms of cardiovascular risk. So they don't necessarily need to change their sodium oxybate medication just because of the sodium content.

But, you know, one thing to keep in mind is there's certain populations where we have to be a little more cognizant of their sodium content. And those include individuals that have a high blood pressure, for instance, also those with heart failure and those with kidney disease. So in patients who have narcolepsy that overlap with those medical conditions, those would be the type of patients that you might consider, you know, whether or not you should switch them to a low-sodium preparation, but the best thing to do is obviously evaluate each patient very carefully and use a little bit of shared decision-making when deciding the best course of treatment for these patients. And it's important to note that there hasn't been really any head-to-head comparisons, for instance, for Xywav versus Xyrem as to the differences in cardiovascular risk.

And an important point is just because Xywav has less sodium, it can't be unequivocally stated that there is a reduced cardiovascular effect.

#### Dr. Thorpy:

So, Clete, what you have indicated is that although 2 of these agents do have extra sodium, we really don't have any data indicating that that sodium has any deleterious effect in the patients with narcolepsy. However, if patients do have some of those risk factors that you mentioned – the cardiovascular problems, the renal problems – then certainly it makes sense to use the low-sodium formulation.

However, not everyone can take the low-sodium formulation. There are benefits to the others. There are people, for example, who have POTS disease with low blood pressure, and then the sodium oxybate actually has some advantage. And of course, there are some patients who can't take the medication twice at night, so the advantage of taking once nightly is a big plus for them if they can't take a second dose. And because, as you have indicated, the risk of heart disease exacerbation by these medications is really very low, and in fact, we don't have any data that show that it does exacerbate heart disease in patients.

Well, this was a brief but great discussion. Unfortunately, our time is up, but thank you for listening.

**Announcer:**

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