



James T. Li, MD, PhD, FAAAAI, Discusses the Risks and Benefits of Primatene Mist

Dave Stukus: Hello. And welcome to Conversations from the World of Allergy, a podcast produced by the American Academy of Allergies, Asthma & Immunology. I'm your host Dave Stukus. I'm a board-certified allergist and immunologist and serve as a social media medical editor for the Academy. Our podcast series will use different formats to interview thought leaders from the world of allergy and immunology. This podcast is not intended to provide any individual medical advice to our listeners. We do hope that our conversations provide evidence-based information. Any questions pertaining to one's own health should always be discussed with their personal physician. The Find an Allergist <http://allergist.aaaai.org/find/> search engine on the academy website is a useful tool to locate a listing of board-certified allergists in your area. Finally, use of this audio program is subject to the American Academy of Allergy, Asthma, & Immunology terms of use agreement which you can find at <http://www.AAAAI.org>. Today is a special edition of our conversations from the world of allergy podcast series. This is our first hot topics recording where we aim to provide timely information to help patients, the general public, and healthcare professionals better understand a current popular topic. We are extremely pleased to welcome Dr. Jim Li who is a professor of medicine at the Mayo Clinic in Rochester, Minnesota. Dr. Li is a former member of the board of directors and past president of the American Academy of Allergy, Asthma & Immunology and previously served as chair of the asthma cough diagnosis and treatment committee. Dr. Li is an internationally recognized expert in asthma, anaphylaxis, and drug hypersensitivity. And has contributed to almost 100 peer-reviewed articles. Today, Dr. Li has graciously agreed to join us to discuss the new FDA announcement regarding approval of over-the-counter Primatene Mist to treat mild asthma. Dr. Li, thank you so much for taking the time to join us today and welcome to the show.

James T. Li: My pleasure, Dave. Glad to be here.

Dave Stukus: Great. Well, let's get into it. Let's start with some basics to make sure our listeners are all on the same page. Can you describe what type of medication Primatene Mist contains?

James T. Li: Yes, Dave. Primatene Mist contains a medication called epinephrine, also known as adrenaline. And it's in an inhaler form and it's designed for use for relief of mild asthma symptoms. It's newsworthy because it's an over-the-counter that is a nonprescription inhaler.

Dave Stukus: Now, we know that Primatene Mist used to be available for patients. But then it was removed from the market. Can you give us some insight as to why it went away? And, also, why the FDA has approved it for use again, now?

James T. Li: Yes, Dave. Well, a number of years back starting in the 1990s, really, but well into the 2000s there was growing concern that the propellants and refrigerants, in fact, in inhalers damaged the ozone layer in the atmosphere. And, therefore, was environmentally unsound. So there was a global decision to phase out these propellants and refrigerants. And, therefore, the propellant in almost all asthma inhalers including Primatene Mist, at the time, were phased out.

Dave Stukus: Interesting. So as it was phased out it had nothing to do with the medication itself but the propellants that were used to express the medicine. Is that correct?

James T. Li: Yes. The reason for the phaseout of Primatene Mist as well as the propellants and other inhalers really was due to environmental concerns. And, of course, in development were alternative propellants that were made available. And so many of the inhalers for asthma that are available now do contain these newer propellants that do not damage the atmosphere. And the new Primatene Mist also uses this newer propellant.

Dave Stukus: Okay. And I'm sure that many of our listeners who have had asthma for many years have noticed the change in their inhalers as they've gone to the pharmacy over the last decade or so.

James T. Li: Well, there was always some concern about the balance between the helpfulness and benefits of Primatene Mist balanced against concerns about safety or the risk of worsening asthma. So that was a point of discussion but that was not the main reason Primatene Mist was phased out back in 2011.

Dave Stukus: Well, if we may let's talk a little bit more about that aspect. You mentioned before that the medication contained inside Primatene Mist is epinephrine. Can you tell our audience a little bit about how epinephrine would help somebody having asthma symptoms?

James T. Li: Yes. Epinephrine, also known as adrenaline, is actually a natural substance that the body makes but it's formulated as a medication in the Primatene Mist inhaler. And it acts as a bronchodilator. So it can open and widen the airways in some patients with asthma. And that's where the benefit of Primatene Mist comes from. Now, there are prescription bronchodilators that contain medications that are somewhat similar to epinephrine but are not epinephrine. And, in fact, for many patients are actually preferable as a bronchodilator. So albuterol or levalbuterol would be two examples of those prescription bronchodilators.

Dave Stukus: That's interesting about the difference in the medications. Can you speak a little bit to the indications of why somebody would use Primatene Mist and what the proper dosage would be?

James T. Li: So Primatene Mist is made available by the FDA as a temporary or short term bronchodilator. So the medication opens up the bronchial tubes for a short period of time meaning a number of hours. So the correct use of the Primatene Mist inhaler would be for the user who has mild intermittent asthma to take one puff and then possibly two puffs of the Primatene Mist for the temporary relief of mild asthma symptoms shortness of breath, wheezing, or chest tightness.

Dave Stukus: And so for somebody with mild asthma, as you mentioned, having symptoms how long would they expect to experience relief of those symptoms from using Primatene Mist.

James T. Li: Well, in the usual situation when symptoms are mild and the Primatene Mist is used appropriately the action probably starts within a number of minutes and may last for a few hours. There are detailed instructions that are enclosed in the package of the Primatene Mist outlining, you know, detailed instructions on how to use the product. For example, if someone with asthma uses the Primatene Mist because they're having trouble breathing or they're wheezing and they're not better that's a clear sign that they need to seek medical attention.

Dave Stukus: And as we mentioned before, of course, anybody who would use this medicine should seek advice from their own personal physician in regards to exactly how they should use it and when.

James T. Li: There are very clear instructions and cautions regarding the use of Primatene Mist. So I already mentioned one of the important, I guess, cautions and that is only patients who have been diagnosed by a healthcare provider with asthma and with mild intermittent asthma should be looking to Primatene Mist as a possible bronchodilator treatment. The other is that the use of Primatene Mist really should be under the guidance of a healthcare provider because there are many other treatments that are available for asthma and for any one person those other treatments actually may be preferable.

Dave Stukus: Now, a lot of people listening may be confused in regards to the diagnosis of asthma. Can you say a few words about how-- what asthma is, how it is diagnosed and how this sort of affects children and adults who have it?

James T. Li: Yes. Asthma is a condition of the bronchial tubes of the airways. It can affect adults and children. And the narrowing of the bronchial tubes with asthma can lead to symptoms such as shortness of breath, wheezing, chest tightness and cough. The diagnosis really must be made by a healthcare provider. And it's based on the details of the medical history as well as typically with laboratory testing including lung function tests.

Dave Stukus: And what types of symptoms with this lead to for people and how would this affect their lives on a regular basis?

James T. Li: Right. So the symptoms are typically chest or respiratory in nature and trouble breathing, trouble breathing with exercise, trouble breathing or wheezing with asthma triggers is typical. The typical triggers for asthma include exercise, cold air, catching a cold and for many patients allergy exposures. But the diagnosis has to be made by a physician or a healthcare provider based on the details of the medical history and some medical tests because there are other important medical conditions that can lead to similar symptoms of shortness of breath and wheezing.

Dave Stukus: Thank you for emphasizing that important point. Now, we haven't had Primatene Mist on the market for some time. And it's not like our patients with asthma have gone without treatment. So can you describe the current treatment approach to asthma?

James T. Li: Yes. There are a number of different treatments available for asthma. Many of the treatment center around medications. Some management strategies actually don't even involve medication. So Dave let me just comment on one or two of those. In particular, if someone with asthma has significant allergies, maybe they're allergic to grass pollen or dust or a cat, if that's diagnosed correctly reducing the exposure can substantially improve asthma symptoms even without medication. But if we talk about medications there are pills for asthma. There are inhaled corticosteroids, a type of inhaler for asthma. There are bronchodilators that are prescription only for asthma. There are even combination inhalers that contain an inhaled corticosteroid plus a bronchodilator in a single inhaler.

Dave Stukus: And in regards to those other types of treatments and inhalers it can become very confusing very quickly for both patients and providers alike. How is the medicine or the epinephrine in Primatene Mist different from these other types of inhalers specifically albuterol or levalbuterol and then the inhaled corticosteroids?

James T. Li: Right. The albuterol and epinephrine are both considered bronchodilators in that they temporarily can open up the bronchial tubes. The inhaled corticosteroids is really a completely different kind of asthma medication that works differently, Dave. The inhaled corticosteroids that are, in fact, quite effective in the control of asthma they're used to reduce the inflammation and the swelling in the lining of the bronchial tubes. They have to be used every day. They're not bronchodilators. But they work very well. They've been around for a few decades now and they're used very successfully. The albuterol or levalbuterol are both bronchodilators that are by prescription only. And many patients with asthma use them very successfully. And they tend to have a lower or better side effect profile than the inhaled epinephrine. The epinephrine is a bronchodilator so it opens up bronchial tubes but it also has potential side effects such as increasing the heart rate or increasing the blood pressure. Those risks are present but much lower in products like albuterol.

Dave Stukus: And would you recommend that anybody with a pre-existing heart condition or other chronic illness discuss the use of Primatene Mist with their personal physician before using it by themselves?

James T. Li: That is important and, in fact, it's written right into the instructions of how to use Primatene Mist and the cautions in using the product. So if someone does have heart disease or high blood pressure they definitely should check with their healthcare provider using Primatene Mist. But I would say all patients who are considering the use of Primatene Mist really should consult their healthcare provider to find out if Primatene Mist is right for them.

Dave Stukus: Great. How would somebody with asthma understand that their asthma is not under good control? And what are some indications when they should seek their own personal physician and better talk about their asthma and ways to get things under control?

James T. Li: Well, the good news here is that almost all patients with asthma under proper management can really gain excellent control over the asthma. And control of asthma means that the person has very few symptoms. And is able to do the things that they want and need to do whether it's work, school,

exercise, recreation whatever. So a healthcare provider who is knowledgeable about the different treatments of asthma can individualize a treatment program to achieve that level of excellent control. So if a person has some wheezing or shortness of breath or asthma symptoms every day or even several times a week that would be an indicator of asthma under less than optimal control. If a person or a child is and not participating in physical activity because of shortness of breath or wheezing that would be another sign that the asthma is not under optimal control. So if someone has any of these symptoms they should see their provider and see if there are treatments that can really get the asthma under perfect control.

Dave Stukus: So this is one area where it sounds safe to say that sort of self-diagnosis and management can be a little tricky and that if people aren't doing well that they should absolutely talk to their doctor.

James T. Li: That is absolutely correct. Getting back to the Primatene Mist one of the reasons that Primatene Mist was approved to become available as a nonprescription medication and to hit the market is because of the detailed instructions that really accompany the use of the drug. So Primatene Mist is only appropriate for someone with physician or provider diagnosed mild intermittent asthma. And the use of Primatene Mist really should be guided by the healthcare provider. And if it's right for that person with asthma who has mild asthma that's intermittent and they use occasional bronchodilator then the over-the-counter product Primatene Mist might be right for that person.

Dave Stukus: And it sounds like the person with asthma who needs to take one or several daily medications to keep their asthma under control that perhaps this is not the best option for them. Would you agree with that?

James T. Li: Well, if someone has more than mild intermittent asthma they definitely should be under the care of a healthcare provider. And they may well require and benefit from a different asthma medication. So we talked about asthma pills, montelukast being one of the most popular prescription pills for asthma. Or one of the inhaled corticosteroid agents that we talked about that can lower the inflammation or swelling in the bronchial tubes. Now, in terms of the short acting bronchodilators usually in that situation the provider might recommend the albuterol or levalbuterol rather than Primatene Mist. But the Primatene Mist under certain circumstances has been used by patients as an emergency bronchodilator. But it's really not indicated for anything more serious than mild intermittent asthma.

Dave Stukus: Now, we've touched upon some of the benefits to using Primatene Mist as you just spoke to. But can you help our audience better understand some of the potential downsides of patients using over-the-counter medications such as Primatene Mist to treat their asthma?

James T. Li: So this has been a topic of concern over many years. There would be at least two categories of caution and concern that I can comment on. The more important one would be that Primatene Mist can mask the deterioration of asthma. So if a patient is in the midst of a progressive asthma attack the use of Primatene Mist potentially could delay the proper treatment of a deteriorating asthma attack that could lead to hospitalization, emergency department visits or even worse. Along with that concern is the, I guess, the caution that if a person with asthma is not under the care of a physician

or healthcare provider then they really should be on different medications and they're putting themselves at risk of asthma attacks or hospitalizations by not getting the proper daily treatment. So that's kind of one category, Dave. The other category is the possible side effects of the epinephrine in Primatene Mist. We already covered increased heart rate, increased blood pressure and other possible side effects that can develop with epinephrine. So a person using Primatene Mist needs to be aware of those potential side effects.

Dave Stukus: Great, thank you. And I think you've done a fantastic job of really breaking down how Primatene Mist differs from other medications and what asthma is and indications for use. But if we could switch gears a little bit as we finish up here we know that many people will cough or wheeze for other reasons aside from asthma such as emphysema or COPD or viral illnesses. Now, is Primatene Mist indicated for these types of conditions as well?

James T. Li: Well, I'm glad you brought that up because it's very clear that the clinical, medical indication for Primatene Mist is only for the temporary relief of asthma symptoms in patients with mild intermittent asthma, really the mildest form of asthma. It is not to be used for any other medical conditions or for other respiratory symptoms. You mentioned COPD or chronic obstructive pulmonary disease. Emphysema is another name for a related condition. These are usually adult patients who have significant smoking histories. People with COPD, also, can have shortness of breath and wheezing just as you describe. Primatene Mist is not indicated for that group. And COPD is a pretty serious medical condition. It's one of the, actually, leading causes of death in adults. So patients with COPD should see their healthcare provider, get on the right treatment, and Primatene Mist would not be right for that person.

Dave Stukus: Great. Thank you for clarifying that. I agree. I think that's an important point that people need to understand. Now, along those lines, since Primatene Mist contains epinephrine people may confuse this with epinephrine delivered through auto injectors which are often prescribed for people with conditions such as food allergies, venom allergies, or anaphylaxis. Can you explain why Primatene Mist is not an effective treatment for anaphylaxis and should never be used in place of an autoinjector?

James T. Li: Well, we know that people who have experienced serious allergic reactions to bee stings, for example, are at risk for future serious allergic reactions or future episodes of anaphylaxis. So for many of these patients we do recommend that they carry epinephrine in the form of a spring-loaded autoinjector. And we provide instructions for such patients so that if they sustain a bee-sting particularly if they are developing a serious allergic reaction they can self-administer the epinephrine in the form of this preloaded syringe and the medication gets into the bloodstream very quickly and it can be lifesaving. So the active ingredients in the epinephrine autoinjector is very similar, if not identical, to the drug or the active ingredient in Primatene Mist. But there's a huge difference because the autoinjector is a preloaded syringe that delivers the epinephrine into the muscle or the bloodstream. Whereas, the Primatene Mist is delivered into the airway and really not enough gets into the bloodstream to be treatment for a bee sting allergy or a food allergy. So anyone who needs epinephrine for a bee sting reaction or anaphylaxis to food should not be thinking of using Primatene Mist but should be using an epinephrine autoinjector instead.

Dave Stukus: Great. Well, Dr. Li thank you so much for taking the time to be with us today on our initial episode of the hot topics as part of our Conversation from the World of Allergy podcast series. Before we depart, do you have any additional thoughts you'd like to share with our listeners regarding Primatene Mist?

James T. Li: Well, I would say if someone is entertaining the possibility of Primatene Mist that they speak to their provider or physician about that possibility. Only patients with the mildest asthma should be using Primatene Mist. And there may be other asthma treatments that might be more suitable for that patient. If it turns out that Primatene Mist is right for that person and that advice is given by a qualified professional it certainly can be helpful for the individual person with asthma.

Dave Stukus: Thank you so much.

James T. Li: Thank you, Dave.

Dave Stukus: We hope you enjoyed listening to today's episode. Please visit <http://www.AAAAI.org> for show notes and any pertinent links from today's conversation. If you like the show, please take a moment to subscribe to our podcast through iTunes or Google play so that you can receive new episodes in the future. Thank you, again, for listening.