

## Methergine Therapy (methylergonovine) Information and Consent

Methergine is a medication which a derivative from the natural occurring ergot fungus. It's close cousin, methysergide (Sansert®) was the first and only medication brought to the market exclusively for migraine and cluster headache prevention and that was in the 1960s. Methysergide was also the most effective treatment for both migraine and cluster headache.

While Sansert® had few side effects and was highly effective, it was discovered after it was on the market for many years that some people, about 4%, who took it chronically developed scar tissue. That scar tissue could be in insignificant places in the body, or it could be in troublesome areas such as on a heart valve. One of the worse case scenarios was if the scar tissue occurred on a heart valve. If it hindered the flow of blood, the patient would require heart surgery to remove it. I have searched the literature extensively and can not find a percentage of patients who had such bad consequences, but it must be very rare.

After this was discovered, Sansert® was continued to be prescribed but with an interruption in therapy every six months, what we call the "Sansert Holiday." It appeared, but was not proven, that this interruption prevented the scar tissue from forming.

Around 2003 the owners of Sansert®, Novartis, decided to stop making it. One reason was the fear that if someone did develop scar tissue they would be sued for tens of millions of dollars. Secondly, it was prescribed only by headache specialists and they really didn't make any money off of it.

About the time that Sansert® had first come to the market its cousin, methergine was introduced specifically to stop post-partum bleeding. It causes the uterus to clap down quicker after giving birth, which stops the bleeding. Because Sansert® wasn't being made anymore, and many patients only were helped by it, headache specialists started using methergine and it appears to be equally effective in headache prevention. The scar tissue, as far we know, has never been reported with methergine, but because it is so similar to Sansert®, you have to assume that it could happen.

Methergine has become a valuable tool in headache treatment because some sufferers only respond to it and nothing else. It doesn't always work but when it does, it can take someone who has severe daily headaches and render them almost headache free, which greatly improves their quality of life. However, because this rare possibility of scar tissue can be serious (if it is on a heart valve) methergine should only be used as last resort and by the clear, informed consent of the patient.

When we use methergine we prescribe it the same way as we did Sansert®, with a "holiday" of 30 days off every six months. I personally recommend doing an ultrasound of the heart every year to catch any evidence of thickening heart valves. The patient

should also be followed in the office every two months so I can listen to their hearts. There is debated about doing other tests, such as CTs of the chest and abdomen. The problem is, while such tests could possibly detect scar early, CTs themselves have risk associated with radiation exposure. There is not a consensus about when to do CT scans so I will offer it to the patient once a year and they can decide, based on the information, which they prefer to do or not.

Besides the risk of scar tissue, methergine tends to have low side effects. It does have other, more rare risks. Because it constricts blood vessels there is a very rare risk of constricting them too far and cutting off blood flow to the hands or feet in condition called “ergotism.” It is so rare that I could not find any statistics of such events with methergine. Methergine should not be used with other vasoconstricting drugs, such as the migraine medications called “triptans” (Imitrex®). This potential of ergotism is also enhanced if the patient uses other drugs that interfere with the enzymes, which break down methergine in the liver. These drugs include anti-fungal pills and some cholesterol lowering agents (see Drug Interactions on the Drug Side Effect List Provided by us and your pharmacist).

By signing below you agree to the following statement: I have read the above information, my questions have been answered and I am willing to take the risk in order to take methergine.

Patient: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Provider: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_