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Headache Toolbox

Breath-Powered Intranasal Sumatriptan Dry Powder

A breath-powered delivery system for sumatriptan dry powder (brand name Onzetra Xsail, Alisa Viejo, CA, USA) is approved by the Food and Drug Administration (FDA) for the treatment of migraine attacks. Sumatriptan is the oldest of the triptan family. Available in the United States in tablet, liquid nasal, injectable, and skin patch forms. In general, triptan medications are taken at the onset of a migraine attack. As a group, they are a specific treatment that delivers relief by targeting the chemicals causing head pain, also treating the ill feelings that make migraines so uncomfortable.

Each form of sumatriptan has its own benefit. Until now, for migraine patients who vomit with their headache attacks, or who need very rapid relief from pain, choices were limited to the inconvenient and painful pinch of the injectable formulation, liquid nasal sprays that mostly go down the throat, or the slower patch.

The breath-powered device delivers 11 mg of sumatriptan dry powder into each nostril for a total dose of 22 mg. The device comes with two nosepieces per treatment (Fig. 1).

First, a clear disposable nosepiece clicks into the reusable device. A white button on the device is pressed to pierce the capsule, releasing the drug into the nosepiece, which is then inserted into the nostril. The user blows forcefully into the mouthpiece, and the powder is delivered to the nasal tissue, blown high up into the nose. When one blows the powder, the back of the palate closes and prevents the powder from going down the throat.

The advantage of this device over tablets is that the medicine is not absorbed through the stomach, whose function is often impaired during a migraine attack. Nasal absorption is fast and not affected by the nausea or gastrointestinal dysfunction typically present during a migraine attack.

The closing of the palate when one blows the drug up the nose prevents the powder from being swallowed, which is a problem with liquid nasal sprays. Swallowing not only decreases how much sumatriptan gets in, but also the drug tastes bad, and this is reduced with the dry powder.

A scientific comparison study was run to compare the sumatriptan breath–powered device with the traditional sumatriptan tablet. Migraine patients were assigned to a traditional, *active* sumatriptan tablet plus an inactive, sham, placebo device, or the *active* breath-powered device plus an inactive tablet (placebo). Of the 174 patients who completed the study, those who used the *active* breath-powered device had significantly greater pain relief than those who took the *active* tablet. This difference in favor of the device held at time points between 30 minutes and 2 hours following the treatment. After 2 hours, the degree of pain relief between the tablet and the breath-powered device merged and remained similar between 2 and 48 hours after the attack. This suggests that the device worked faster than the tablet for up to 2 hours.

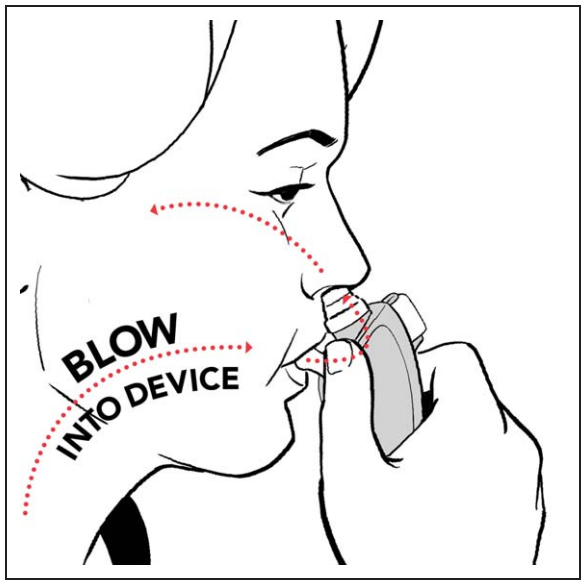

Fig. 1.—The user blows with their mouth into the device to deliver sumatriptan into their nose.

A second study evaluated the effectiveness and safety of the device, comparing it with an identical device loaded with an inactive placebo powder. In this study, 223 patients received either an active or inactive device, and headache relief was measured at 2 hours. In the active group, 68% reported headache relief, while 45% of those in the inactive placebo group experienced this benefit. There was a significant difference in which the active drug worked better as early as 30 minutes after it was taken. The improvement was maintained even at 48 hours after the dose was given. Total pain freedom, a much harder standard to meet because it includes no headache, no nausea, and no light or noise sensitivity, occurred at 1 hour in 19% of those who received the active drug through the inhaler.

There were no serious side effects in the safety study, and no one who used the active device developed the common triptan sensation of chest tightness. Side effects described include an abnormal taste in 22% of those receiving the active drug vs 4% of those getting inactive device (placebo), nasal discomfort in 13% with the active drug vs 2% placebo, and nose running or congestion in 3–5% of those in the active drug group. The abnormal taste from the sumatriptan powder was rated as mild by 90% of those who reported it. A single patient described a mild skin sensation. No significant changes were found in laboratory testing, heart tracing (electrocardiogram [ECG]), blood pressure, or heart rate.

In summary, this delivery system for sumatriptan, the tried and true acute migraine drug, provides a novel way to treat migraine quickly and effectively, even in those with nausea and vomiting. Unlike the traditional nasal sprays, it does not drip down into the throat, and unlike the injectable form of sumatriptan, it is painless and does not involve needles. The side effects such as chest tightness so bothersome with tablet and shot were less with this device, and when directly compared with the tablet, the breath powered nasal dry powder worked faster at every time point checked up to 2 hours. Unfortunately, insurance coverage for this delivery system may be initially challenging, as generic formulations of sumatriptan tablets are tops on any formulary now. However, a tablet formulation is not appropriate with nausea and vomiting, so this device may prove appropriate for the individual who needs fast, non-oral relief.

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