SOLRIAMFETOL (Sunosi) Fact Sheet

Bottom Line:

Solriamfetol is a wakefulness promoter with a different mechanism of action from modafinil and armodafinil. Patients may ask you about it given all the TV ads, but time will tell how it compares with these more established (and cheaper) agents.

FDA Indications:

Excessive daytime sedation (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).

Off-Label Uses:

ADHD; fatigue; treatment-resistant depression.

Dosage Forms:

Tablets: 75 mg, 150 mg (scored).

Dosage Guidance:

Start 37.5 mg QAM for sleep apnea or 75 mg QAM for narcolepsy. Increase dose at intervals of at least three days. Max dose 150 mg/day.

Monitoring: No routine monitoring recommended unless clinical picture warrants.

Cost: \$\$\$\$\$ **Side Effects:**

• Most common: Headache, nausea, decreased appetite, and anxiety.

• Serious but rare: Increased blood pressure and pulse; psychosis or mania may occur.

• Pregnancy/breastfeeding: Not enough data to recommend.

Mechanism, Pharmacokinetics, and Drug Interactions:

- Dopamine and norepinephrine reuptake inhibitor (DNRI).
- Not metabolized, renally eliminated; t ½: 7 hours.
- Avoid MAOIs.

Clinical Pearls:

- This new wake-promoting drug was approved based on four studies of more than 900 adults with narcolepsy or OSA. For example, in a 12-week randomized double-blind controlled trial of 239 adults with narcolepsy, 150 mg/day of Sunosi (but not 75 mg/day) showed statistically significant improvement on tests of wakefulness.
- In a similar study of 476 adults with OSA, patients receiving 37.5 mg/day, 75 mg/day, and 150 mg/day of Sunosi showed statistically significant improvement over placebo at week 12.
- Maintenance of efficacy of up to 50 weeks was shown in two open-label extension studies of patients with EDS associated with either narcolepsy or OSA.
- Given that Sunosi is a DNRI (like bupropion), there has been interest in studying the drug for depression, though clinical trials have not yet been conducted.
- Sunosi has demonstrated abuse potential, particularly at doses higher than recommended for EDS, and has been classified as a controlled substance (Schedule IV).

Sunosi is manufactured by Jazz Pharmaceuticals, the company that sold \$1.4 billion of Xyrem (sodium oxybate) in 2018. Now that the FDA has approved generic versions of Xyrem, Jazz will likely be looking at Sunosi as their biggest profit-maker.

