

Sympazan™ (clobazam) – New drug approval

- On November 2, 2018, [Aquestive Therapeutics announced](#) the FDA approval of [Sympazan \(clobazam\)](#) oral film, for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.
 - Sympazan is a Schedule IV controlled substance.
- LGS is a severe form of epilepsy that begins in early childhood and is characterized by multiple types of seizures and intellectual disability.
- The exact mechanism of action for clobazam is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA_A receptor.
- Clobazam is also available generically as a [tablet](#) and [oral suspension](#).
 - Generic clobazam shares the same indication as Sympazan.
- The approval of Sympazan is based upon efficacy studies conducted for clobazam tablets and pharmacokinetic studies comparing clobazam tablets to Sympazan. Sympazan oral film at single doses of 10 mg and 20 mg clobazam have been shown to be bioequivalent to clobazam tablets at equivalent doses.
- Sympazan carries a boxed warning for risks from concomitant use with opioids.
- Warnings and precautions of Sympazan include potentiation of sedation from concomitant use with central nervous system depressants; somnolence or sedation; withdrawal symptoms; serious dermatological reactions; physical and psychological dependence; and suicidal behavior and ideation;
- The most common adverse reactions (≥ 10% more frequently than placebo) with clobazam use include constipation, somnolence or sedation, pyrexia, lethargy, and drooling.
- The recommended dose of Sympazan is weight-based and given orally with or without food. Each dose in the table below has been shown to be effective, although effectiveness increases with increasing dose.

	Body weight ≤ 30 kg	Body weight > 30 kg
Starting dose	5 mg	10 mg
Starting day 7	10 mg	20 mg
Starting day 14	20 mg	40 mg

- Sympazan should be applied on top of the tongue where it adheres and dissolves.
- Sympazan should not be administered with liquids.
- Doses > 5 mg should be administered in divided doses twice daily. A daily dose of 5 mg can be administered as a single dose.

- Aquestive Therapeutics plans to launch Sympazan in November 2018. Sympazan will be available as 5 mg, 10 mg, and 20 mg oral film.



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