As you may know, the Tris family of Attention Deficit Hyperactivity Disorder (ADHD) extended-release products utilize Liqui*XR*® technology which enables flexible dosing of our products.

Quillivant XR® (methylphenidate HCl) for extended-release oral suspension, 25 mg/5 mL	QuilliChew ER® (methylphenidate HCl) extended-release chewable tablets, 20 mg, 30 mg, 40 mg	Dyanavel XR® (amphetamine) extended-release oral suspension 2.5 mg/mL
The first once-daily, extended-release liquid methylphenidate	**The only methylphenidate scored tablet that can be chewed or swallowed whole**	**The first once-daily, extended-release liquid amphetamine**
Formulation **Liquid**	Formulation **Tablet**	Formulation **Liquid**
Dosing **Flexible dosing**	Dosing **The most dosing options of any extended-release tablet methylphenidate**	Dosing **Titration within one prescription**

INDICATION

DYANAVEL® XR (amphetamine), Quillivant XR® (methylphenidate HCl), and QuilliChew ER® (methylphenidate HCl) are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including DYANAVEL XR, Quillivant XR, QuilliChew ER, and other amphetamine-containing or methylphenidate-containing products, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

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Get more information on these products and see how you can individualize your patients' dosage at **TrisADHDhcp.com**

Birgit H. Amann, MD
Child, Adolescent
and Adult Psychiatry

Hear one physician's experience with individualized dosing at: TrisADHDhcp.com/DrAmann

IMPORTANT SAFETY INFORMATION (cont'd)

- DYANAVEL XR (amphetamine), Quillivant XR (methylphenidate HCl), and QuilliChew ER (methylphenidate HCl) are contraindicated:
  - in patients known to be hypersensitive to amphetamine, methylphenidate, or other components of DYANAVEL XR, Quillivant XR, and QuilliChew ER. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported.
  - in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs, because of risk of hypertensive crisis.
- Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, and other serious cardiac problems. Sudden death, stroke, and myocardial infarction have been reported in adults treated with CNS stimulants at recommended doses. Sudden death has been reported in pediatric patients with structural cardiac abnormalities and other serious cardiac problems when taking CNS stimulants at recommended doses for ADHD. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during treatment with DYANAVEL XR, Quillivant XR, and QuilliChew ER.
- CNS stimulants cause increase in blood pressure (mean increase approximately 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Monitor all patients for tachycardia and hypertension.
- CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a preexisting psychotic disorder. They may induce a mixed/manic episode in patients with bipolar disorder. Assess for presence of bipolar disorder prior to initiating treatment. At recommended doses, stimulants may cause psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania, in patients without prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing DYANAVEL XR, Quillivant XR, or QuilliChew ER.
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients with ADHD; monitor weight and height during treatment with DYANAVEL XR, Quillivant XR, and QuilliChew ER. Treatment may need to be interrupted in children not growing or gaining weight as expected.
- CNS stimulants are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.
- Serotonin syndrome risk is increased when DYANAVEL XR is co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans), MAOIs, and during overdosage situations. If it occurs, discontinue DYANAVEL XR and any concomitant serotonergic agents immediately, and initiate supportive treatment.
- QuilliChew ER contains phenylalanine, a component of aspartame, and can be harmful to patients with phenylketonuria (PKU).
- Most common adverse reactions observed with **amphetamine products**: dry mouth, anorexia, weight loss, abdominal pain, nausea, insomnia, restlessness, emotional lability, dizziness, and tachycardia.
- Based on limited experience with DYANAVEL XR in controlled trials, the adverse reaction profile of DYANAVEL XR appears similar to other amphetamine extended-release products. The most common (≥2% in the DYANAVEL XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 108 patients with ADHD (aged 6 to 12 years) were: epistaxis (DYANAVEL XR 4%, placebo 0%), allergic rhinitis (4%, 0%) and upper abdominal pain (4%, 2%).

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IMPORTANT SAFETY INFORMATION (cont'd)

- Based on accumulated data from other **methylphenidate products**, the most common (≥5% and twice the rate of placebo) adverse reactions are: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, blood pressure increased.
- There is limited experience with Quillivant XR (methylphenidate HCl) and QuilliChew ER (methylphenidate HCl) in controlled trials.
  - Quillivant XR: The most common (≥2% in the Quillivant XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 45 ADHD patients (ages 6 to 12 years) in Quillivant XR compared to placebo were affect lability (9% Quillivant XR, 2% placebo), excoriation (4%, 0%), initial insomnia (2%, 0%), tic (2%, 0%), decreased appetite (2%, 0%), vomiting (2%, 0%), motion sickness (2%, 0%), eye pain (2%, 0%), and rash (2%, 0%).
  - QuilliChew ER: The most common (≥2% in the QuilliChew ER group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 90 pediatric subjects (ages 6 to 12 years) in QuilliChew ER compared to placebo were decreased appetite (2.4% QuilliChew ER, 0% placebo), aggression (2.4%, 0%), emotional poverty (2.4%, 0%), nausea (2.4%, 0%), headache (2.4%, 0%), and weight decreased (2.4%, 0%).
- DYANAVEL XR (amphetamine), Quillivant XR, and QuilliChew ER use during pregnancy may cause fetal harm.
- Breastfeeding is not recommended during treatment with DYANAVEL XR, Quillivant XR, or QuilliChew ER.

Please see accompanying Full Prescribing Information for DYANAVEL XR, Quillivant XR, and QuilliChew ER, including Boxed Warning regarding Abuse and Dependence, in envelope.

Tris PHARMA