Two new stimulant formulations were approved in 2015: QuilliChew ER and Dyanavel XR. QuilliChew ER is a long-acting methylphenidate chewable tablet that allows once-daily dosing. Dyanavel XR is an amphetamine liquid formulation containing a 3.2 to 1 ratio of d- to l-amphetamine.

**QuilliChew ER**

Approval date: December 7, 2015  
Pfizer Inc  
Available in pharmacies (US): First quarter of 2016

**FDA-approved indication**

- Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years and older

**Pharmacology and delivery technology**

Methylphenidate is a racemic mixture comprised of the d- and l-isomers. The d-isomer is more pharmacologically active than the l-isomer.

QuilliChew ER contains approximately 30% immediate release and 70% extended release methylphenidate.

The QuilliChew ER extended-release chewable tablets are cherry flavored.

**Dosage and administration**

- It may be taken with or without food  
- For patients 6 years and above, the recommended starting dose is 20 mg given orally once daily in the morning.
• Dosage may be titrated weekly in increments of 10 mg, 15 mg or 20 mg per day.
• Daily dosage above 60 mg is not recommended.

Dosage forms and strengths

• Extended-release chewable tablets: 20 mg and 30 mg of methylphenidate hydrochloride (HCl), functionally scored
• Extended-release chewable tablets: 40 mg of methylphenidate HCl, not scored

Comment

QuilliChew ER is a new long-acting methylphenidate formulation. Methylin CT is also a methylphenidate formulation already available as chewable tablet.

The difference is that Methylin CT is a short-acting formulation, while QuilliChew ER offers the advantage of once-daily dosing.

Dyanavel XR (amphetamine) extended-release oral suspension

Approval date: October 20, 2015
Tris Pharma
Available in pharmacies (US): First quarter of 2016

FDA-approved indication

• Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years and older

Pharmacology and delivery technology

• Extended release liquid formulation containing a 3.2 to 1 ratio of d- to l-amphetamine.
• Each 1 ml contains 2.5 mg of amphetamine which is the same as the amount of amphetamine (base equivalent) found in a 4 mg strength amphetamine mixed salts product.
• Dyanavel XR contains immediate release and extended release components.
Dosage and administration

- Before administering the dose, shake bottle
- May be taken with or without food
- In children 6 years of age and older, recommended starting dose is 2.5 mg or 5 mg once daily in the morning
- Dosage may be increased in increments of 2.5 mg to 10 mg per day every 4 to 7 days until optimal response is obtained
- Daily dose above 20 mg is not recommended
- Do not substitute for other amphetamine products on a milligram-per-milligram basis, because of different amphetamine base compositions and differing pharmacokinetic profiles

Dosage forms

- Extended-release oral suspension containing 2.5 mg amphetamine base per mL

Comment

Dyanavel XR is a new amphetamine liquid formulation containing a 3.2 to 1 ratio of d- to l-amphetamine. Another liquid formulation is already available: Quillivant XR (Methylphenidate).

There are now liquid formulations available for both methylphenidate (Quillivant XR) and amphetamine (Dyanavel XR) - this applies to the US market only.

References