No food effect was observed for AMPH ER TAB administered chewed. All AEs were mild in severity and AE profiles were similar to other amphetamine formulations used for treatment of ADHD.
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179
Palatability Assessment of a New Amphetamine Extended-Release Tablet Formulation

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ABSTRACT: Background: In 2016, the US FDA issued an industry guidance document "Quality Attribute Considerations for Chewable Tablets" which describes the quality attributes to be considered when developing chewable tablets. It includes recommendations on selection of acceptance criteria for measuring palatability (having a taste acceptable to the patient or has adequate masking). These data are now recommended as part of ANDA submissions. Palatability is a known positive contributing factor to drug adherence and persistence. We summarize here palatability data for a new amphetamine extended-release tablet (Dyanavel XR® Extended Release Tablet; AMPH ER TAB).

METHODS: This was a 2-arm preplanned secondary analysis from a comparative bioavailability study: single-dose AMPH ER TAB 20 mg chewed under fasting (Treatment A) and fed (Treatment B) conditions. Subjects rated the palatability of AMPH ER TAB (Treatments A+B) through a 5-question palatability questionnaire. The questions included in the palatability questionnaire were as follows:

1. Oral sensation/mouth feel of the drug product
2. Taste of the drug product
3. How strong is the taste?
4. Aftertaste of the product
5. How strong is the aftertaste?

Subjects completed the questionnaire within 10 minutes from the time of drug administration, which was evaluated and scored according to the rubric below:
Q1, Q2, Q4: palatability- Very unpleasant (score of 1), Unpleasant (2), No sensation or mouthfeel (3), Pleasant (4), and Very pleasant (5)
Q3, Q5 (Taste/aftertaste strength): Very strong (score of 1), Strong (2), Moderate (3), Mild (4), No aftertaste (5).
Scores of 1-2 for both categories were Negative; score of 3 was Neutral, and 4-5 were Positive.

RESULTS: 35 subjects comprised the palatability dataset (completed one question on the questionnaire). In the palatability analysis, for treatments A and B, most of the subjects rated the oral sensation/mouth feel of AMPH ER TAB (Question 1) and the taste of AMPH ER TAB (Question 2) as positive (pleasant to very pleasant) (70.1% and 83.6%, respectively). When evaluating taste strength (Question 3): 43.3% rated the strength as positive (mild/no taste) and 43.3% of subjects rated the strength as neutral (moderate taste). Also, 82.1% rated the aftertaste of AMPH ER TAB (Question 4) as positive (pleasant/very pleasant) and 52.2% rated the strength of the aftertaste as positive (mild/no taste).

CONCLUSION: Most subjects rated the oral sensation and taste as pleasant or very pleasant, whether chewed under fasted conditions or after a meal. With respect to the taste strength, most subjects rated it as moderate (chewed under fasted conditions) or mild/no taste (chewed after a meal). Aftertaste was rated as pleasant or very pleasant in most subjects, with the strength as moderate (chewed under fasted conditions) or mild/no aftertaste (chewed after a meal). AMPH ER Tablets provided an overall pleasant taste and mouthfeel experience for patients.
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180
Improvement of Sexual Function Observed During Treatment of Major Depressive Disorder with Adjunctive Pimavanserin

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