

Buprenorphine ER (Brixadi®): Adis Evaluation

Clinical Considerations

- Novel long-acting formulation using FluidCrystal® injection depot technology
- Administered weekly or monthly as a subcutaneous injection
- Non-inferior to sublingual buprenorphine/naloxone
- Associated with high levels of treatment satisfaction
- Generally well tolerated

Plain Language Summary

Background and rationale

- Opioid use disorder (OUD) is the long-term use of opioids that adversely affects physical and mental health
- Treatment of OUD is based on psychosocial support and the use of opioid agonists to reduce illicit opioid use, craving, and HIV risk
- The partial opioid agonist buprenorphine extended-release (ER) injection for subcutaneous use (Brixadi®; CAM2038; hereafter referred to as buprenorphine ER) is approved for patients with OUD who have started treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine
- The drug is released continuously over one week or one month

Clinical findings

- In a phase 3 trial in patients with OUD, weekly or monthly subcutaneous buprenorphine ER was not inferior to daily sublingual buprenorphine/naloxone in terms of a response to treatment (measured by urine drug screening and self-reporting of illicit opioid use)
- Buprenorphine ER was generally well tolerated; the most commonly reported adverse events were reactions at the injection site

Conclusion

Weekly or monthly subcutaneous buprenorphine ER is a useful addition to the treatment options for OUD.

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