Bunavail® (buprenorphine/naloxone) – Expanded indication

- On April 27, 2017, the FDA approved BioDelivery Sciences' Bunavail (buprenorphine/naloxone) buccal film, for the treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support.

    — This new approval expands the use of Bunavail to include induction treatment of opioid dependence.
    — Previously, Bunavail was only approved for the maintenance treatment of opioid dependence.

- Under the Drug Addiction Treatment Act, prescription use of this product in the treatment opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

- To avoid precipitating withdrawal, induction with Bunavail should be undertaken when objective and clear signs of withdrawal are evident, and Bunavail should be administered in divided doses when used as initial treatment.

    — For patients dependent on short-acting opioid products who are in opioid withdrawal, on day 1, administer up to 4.2 mg/0.7 mg of Bunavail in divided doses. On day 2, administer up to 8.4 mg/1.4 mg of Bunavail as a single dose.
    — For patients dependent on methadone or long-acting opioid products, induction using sublingual buprenorphine monotherapy is recommended.
    — Bunavail should be applied to the buccal mucosa. Bunavail should not be cut, torn, chewed, or swallowed.

- The recommended target dose of Bunavail for maintenance therapy is 8.4 mg/1.4 mg as a single daily dose.