The objective of this study was to evaluate the safety and tolerability of the fentanyl buccal soluble film (Breakyl®) when used in the treatment of breakthrough cancer pain.

RESEARCH AIMS

The overall AE profile appears consistent with use of an opioid in patients with cancer and chronic pain. The AE that were attributed to study drug by the investigator and that occurred in at least 5% of patients were nausea (8.6%), dizziness (5.5%), and constipation (5.0%).

SAFETY:

- The incidence of AEs increases with duration of exposure, as expected and there was no relationship between incidence of AEs and age, gender or ethnic origin.
- Three (1.4%) patients experienced AEs involving the mouth that are possibly related to the buccal film; each of these was of mild severity that did not warrant study drug discontinuation.

CONCLUSIONS

- The fentanyl buccal soluble film is effective and well tolerated in patients with cancer breakthrough pain, being the suggested dose range (200 to 1200 µg) adequate for the majority of patients.
- Of note is the good acceptability of the product by patients and its excellent local tolerability.