

## Clinical summary

**A randomised, controlled, examiner-blind, clinical study investigating the effects of a dentifrice containing 67% sodium bicarbonate when used twice daily for 12 weeks on gingivitis treatment and plaque removal.**

Haleon Data on File, 300029, 2023

### Aim

To investigate the efficacy of a toothpaste containing 67% w/w sodium bicarbonate and 0.31% w/w sodium fluoride, without professional pre-prophylaxis, in gingivitis treatment and plaque reduction, and compare it to a marketed regular fluoride toothpaste after 12-week twice daily brushing.

### Study products and usage

- Test dentifrice: containing 67% sodium bicarbonate and 0.31% w/w sodium fluoride (Corsodyl toothpaste)
- Regular fluoride dentifrice: (Colgate Cavity Protection toothpaste)

### Method

- Single-centre, controlled, examiner-blind, randomised, two-treatment arm, parallel study in volunteers with clinically measurable levels of gingivitis 188 evaluable subjects completed the study.
- Inclusion criteria: (At screening visit 2) 10-30% bleeding sites, mean whole mouth TPI score > 1.5 and a pocket depth < 3 mm (updated classification of localised gingivitis).
- Unlike with previous clinical studies for Corsodyl 67% sodium bicarbonate toothpaste, there was no professional pre-prophylaxis at Screening or Baseline.
- Once randomised, subjects underwent a supervised brushing and were instructed to use their test toothpaste twice daily until their next visit.
- Subjects were asked to attend for visits at week 3, 6 and 12 with overnight plaque.

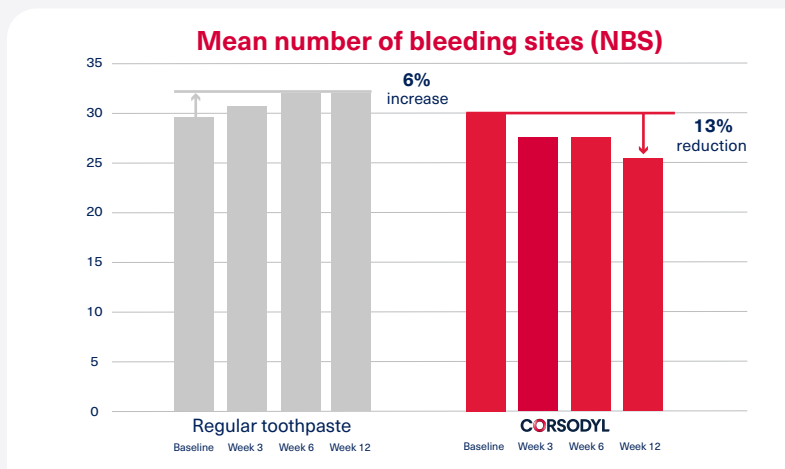
## Conclusions

- This study proves the efficacy of Corsodyl toothpaste with 67% sodium bicarbonate on improving localised levels of gingivitis (updated classification of periodontal health) following 12 weeks twice daily brushing in a population without a professional pre- prophylaxis prior to treatment. These results were seen as early as 3 weeks of use.
- There was a significant improvement in gingivitis (assessed by NBS, BI and MGI) and plaque removal following twice daily use of Corsodyl for 3, 6 and 12 weeks except for the number of bleeding sites at 6 weeks.
- 25% of patients were free from gingivitis following 12 weeks use of Corsodyl, almost twice more than those using regular toothpaste.
- There was a statistically significant greater reduction in the number of bleeding sites, BI, MGI and TPI (overall and interproximal) within the Corsodyl toothpaste group, compared to the regular toothpaste after 3, 6 and 12 weeks.

## Results

### Mean number of bleeding sites (NBS)

- There was a statistically significant reduction ( $p=0.0032$ ) in the NBS from Baseline to week 12 for the Corsodyl group.
- There was a statistically significant greater reduction in the NBS from Baseline to week 12 for the Corsodyl group compared to the regular toothpaste group.

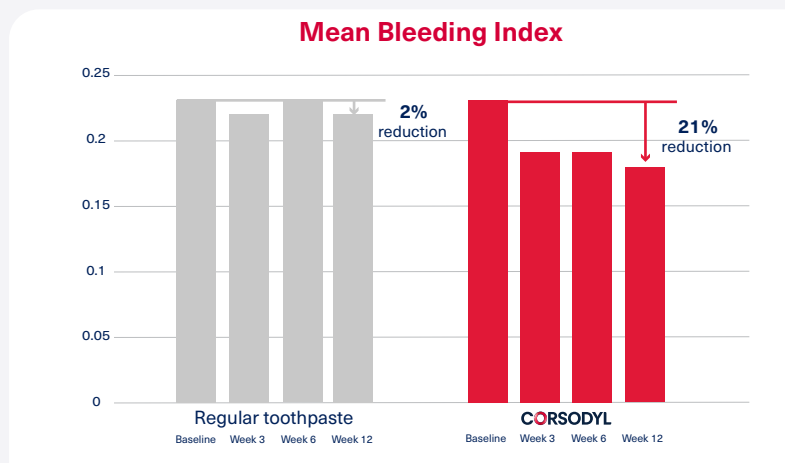


**73%**

of people saw an improvement in the number of bleeding sites at 12 weeks vs Baseline

### Mean bleeding index

- There were statistically significant reductions (all  $p<0.0001$ ) from Baseline in the Corsodyl group at 3, 6 and 12 weeks.
- There were statistically significantly greater reductions for the Corsodyl toothpaste compared to the regular toothpaste at 3, 6 and 12 weeks.

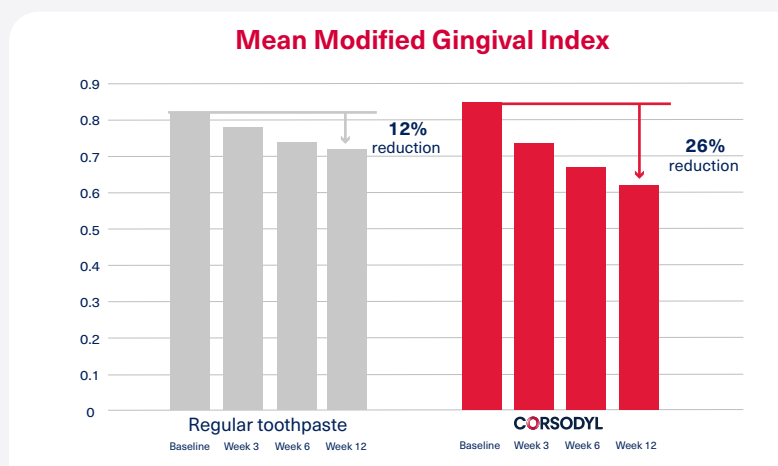


**63%**

of people saw a statistically significant reduction in bleeding and inflammation at 3 weeks vs Baseline.

## Mean modified gingival index

- Statistically significant reductions (all  $p < 0.0001$ ) from Baseline in the Corsodyl group compared to the regular toothpaste at 3, 6 and 12 weeks.
- Subjects using Corsodyl toothpaste showed improvements from as early as week 3 and improvements were seen for over 80% of patients at the end of the 12-week treatment period.
- There was a 26% reduction in mean modified gingival index at the end of the 12-week treatment period compared to a 12% reduction for the regular fluoride toothpaste.

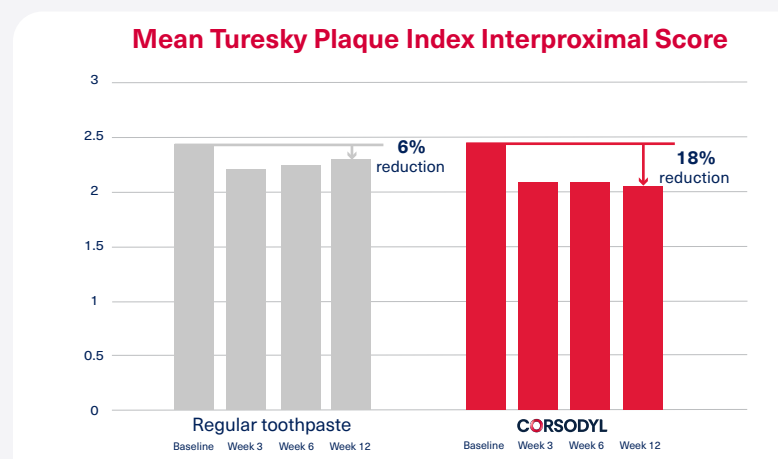


**26%**

reduction in mean modified gingival index at the end of the 12-week treatment period.

## Mean Turesky plaque index

- Results show improvements in PI for patients using Corsodyl (as measured using overnight plaque) with localised (mild) gingivitis from as early as 3 weeks which improved through the 12-week period.
- There were statistically significant reductions (all  $p = 0.0001$ ) from Baseline in the Corsodyl toothpaste group at 3, 6 and 12 weeks for overall TPI and interproximal TPI.
- 25% of patients were free from gingivitis following 12 weeks of use of Corsodyl, almost twice more than those using regular toothpaste.



**18%**

reduction in interproximal TPI at week 12 highlights improved performance even in hard-to-reach areas vs regular toothpaste.