Stoma Product Assessment Panel Public Summary Documents

Omnigon – 12 November 2024

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# Omnigon Ten Aces Med – Medical Adhesive Spray – OG#01NOVEMBER2024

## Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon, sought listing of Omnigon Ten Aces Med – Medical Adhesive Spray in subgroup 9(m) of the Stoma Appliance Scheme (SAS) Schedule. The product, including one variant, was proposed for listing at a unit price of $35.650, with a pack size of one unit and a maximum monthly quantity of one unit with an R1 restriction[[1]](#footnote-1).

## Comparator

The applicant did not nominate a comparator product.

## Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

## Clinical Analysis

The proposed product would provide an alternative for users requiring an adhesive spray. The Panel noted there are no similar products currently available on the SAS Schedule and that the proposed product has limited use in stoma management. The Panel questioned the necessity of the product for use in stoma care, noting it could negate the benefits of self‑adhesive products. The Panel noted the product information states that the product should not be applied directly to the skin and contains hazardous material. The Panel were concerned about the safety implications if the product was misused and applied directly to the skin.

## Economic and Financial Analysis

The Panel noted there are no comparator products currently available on the SAS Schedule. Should the listing of this product be recommended in the future, there would likely be an increased cost to the SAS.

## Panel Recommendation

The Panel rejected the application for Omnigon Ten Aces Med – Medical Adhesive Spray to be listed in subgroup 9(m) of the SAS Schedule with one variant, at the unit price of $35.650, with a pack size of one unit and a maximum monthly quantity of one unit with an R1 restriction, noting concerns about the suitability of the product in stoma care and safety concerns with potential misuse.

## Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. Panel advice not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. An applicant can resubmit to the Panel following advice not to recommend listing or changes to a listing.

## Applicant’s Comment

The applicant noted the recommendation.

# Omnigon Eakin Dot 1 Piece Soft Convex High Output – OG#02NOVEMBER2024

## Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon, sought listing of an additional 2 variants of Omnigon Eakin Dot 1 Piece Soft Convex High Output in subgroup 11(a) of the Stoma Appliance Scheme (SAS) Schedule. The was additional variants were proposed for listing at a unit price of $22.330, with a pack size of 10 units and maximum monthly quantity of 20 units.

## Comparator

The applicant nominated Omnigon Eakin Dot 1 Piece Soft Convex High Output (80229N) as the comparator. The comparator product (2 variants) is currently listed in subgroup 11(a) of the SAS Schedule at a unit price of $22.330, with a pack size of 10 units and a maximum monthly quantity of 20 units.

## Background

This application was to add 2 variants to the existing product range of Omnigon Eakin Dot 1 Piece Soft Convex High Output (SAS code 80229N).

## Clinical Analysis

The Panel noted that the additional variants would provide alternatives for users seeking a clear pouch option and additional colours.

## Economic and Financial Analysis

The Panel noted that the listing of this product at the same price and same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

## Panel Recommendation

The Panel recommended an additional 2 variants of the Omnigon Eakin Dot 1 Piece Soft Convex High Output be listed in subgroup 11(a) of the SAS Schedule at a unit price of $22.330, with a pack size of 10 units and a maximum monthly quantity of 20 units. The product codes of the new variants are to be listed under the existing SAS code of 80229N.

## Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

## Applicant’s Comment

The applicant noted the recommendation.

# Omnigon KomfortLite Paediatric Support Belt – OG#03NOVEMBER2024

## Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon, sought listing of Omnigon KomfortLite Paediatric Support Belt in subgroup 9(h) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 4 variants, was proposed for listing at a unit price of $45.150, with a pack size of one unit and a maximum annual quantity of 4 units.

## Comparator

The applicant nominated Omnigon KomfortLite Support Belt (80232R) as the comparator. The comparator product (20 variants) is currently listed in subgroup 9(h) of the SAS Schedule at the unit price of $45.150, with a pack size of one unit, a maximum annual quantity of 4 units and an R2 restriction[[2]](#footnote-2).

## Background

This was the Stoma Product Assessment Panel’s (the Panel) first consideration of this product.

## Clinical Analysis

The proposed product is a new product range for users requiring a paediatric support belt. The Panel noted the new product range will be beneficial to paediatric ostomates who are at greater risk of hernias and prolapse due to rolling and turning which impacts appliance security. The Panel noted the use of a support belts in the paediatric population is supported by the Wound Ostomy and Continence guidelines.

## Economic and Financial Analysis

The Panel noted that the listing of this new product at the same price and the same maximum annual quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

## Panel Recommendation

The Panel recommended the Omnigon KomfortLite Paediatric Support Belt be listed in subgroup 9(h) of the SAS Schedule with 4 variants, at the unit price of $45.150, with a pack size of one unit and a maximum annual quantity of 4 units.

## Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

## Applicant’s Comment

The applicant noted the recommendation.

# Omnigon Eakin Freeseal – OG#04NOVEMBER2024

## Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon, sought listing of an additional 4 variants of Omnigon Eakin Freeseal in subgroup 9(l) of the Stoma Appliance Scheme (SAS) Schedule. The additional variants were proposed for listing at a unit price of $4.531, with a pack size of 10 units and maximum monthly quantity of 30 units.

## Comparator

The applicant nominated Omnigon Eakin Freeseal (80227L) as the comparator. The comparator product (one variant) is currently listed in subgroup 9(l) of the SAS Schedule at a unit price of $4.531, with a pack size of 10 units and a maximum monthly quantity of 30 units.

## Background

This application was to add 4 variants to the existing product range of Omnigon Eakin Freeseal (SAS code 80227L).

## Clinical Analysis

The additional variants provide alternatives for users requiring a seal product. The Panel noted the new variants come in a range of sizes and have a thicker composition.

## Economic and Financial Analysis

The Panel noted that the listing of the additional variants at the same price and same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

## Panel Recommendation

The Panel recommended an additional 4 variants of the Omnigon Eakin Freeseal be listed in subgroup 9(l) of the SAS Schedule at a unit price of $4.531, a pack size of 10 units and a maximum monthly quantity of 30 units. The product codes of the new variants are to be listed under the existing SAS code 80227L.

## Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

## Applicant’s Comment

The applicant noted the recommendation.

# Omnigon Deletion Requests – November 2024

## Proposed Deletions on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of the following listings:

| Application ID | Group ID | SAS Code | Brand Name | Pack Size | Max Qty | Unit Price | Price Premium | Total company codes | Company code/s being deleted |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OG#05 | 1c | 80166G | Omnigon Welland Aurum Profile | 10 | 60m | 4.433 | N/A | 30 | XMHCCM413  XMHCCM519  XMHCCM522  XMHCCM919  XMHCCM922  XMHCCS413 |
| OG#06 | 2b | 80167H | Omnigon Welland Aurum Profile | 10 | 30m | 6.373 | N/A | 33 | XMHCDS413  XMHCDX113 |
| OG#07 | 3b | 80168J | Omnigon Welland Aurum Profile | 10 | 30m | 6.373 | N/A | 28 | XMHCUS519 |
| OG#08 | 1c | 3945P | Omnigon Welland Aurum Convex Closed | 10 | 60m | 4.433 | N/A | 22 | XMHNCS413  XMHNCS919 |
| OG#09 | 2b | 3946Q | Omnigon Welland Aurum Convex Drainable | 10 | 30m | 6.373 | N/A | 21 | XMHNDS413  XMHNDS519  XMHNDS919 |
| OG#10 | 3b | 3947R | Omnigon Welland Aurum Convex Urostomy | 10 | 30m | 6.373 | N/A | 23 | XMHNUS919 |
| OG#11 | 1c | 3948T | Omnigon Welland Flair Active Curvex Closed | 10 | 60m | 4.433 | N/A | 10 | XPCCM713  XPCCS513  XPCCS713 |
| OG#12 | 2b | 3949W | Omnigon Welland Flair Active Curvex Drainable | 10 | 30m | 6.373 | N/A | 10 | XPCDM713  XPCDS513  XPCDS713 |
| OG#13 | 3b | 3950X | Omnigon Welland Flair Active Curvex Urostomy | 10 | 30m | 6.373 | N/A | 14 | XPCUS713  XPCUS522  XPCUS519 |
| OG#14 | 2a | 9780R | Omnigon Welland Flair Active | 30 | 30m | 4.674 | N/A | 21 | XPLD732 |
| OG#15 | 1b | 9781T | Omnigon Welland Flair Active | 30 | 90m | 2.735 | N/A | 28 | XPLC732  XPLC735  XPLC744  XPMC544  XPMC713  XPMC725  XPMC729  XPMC732  XPMC735  XPMC738  XPMC744 |
| OG#16 | 3a | 9784Y | Omnigon Welland Flair Active | 10 | 60m | 4.674 | N/A | 7 | XPUR519 |
| OG#17 | 5a | 80083X | Omnigon Welland Aurum 2 | 30 | 90m | 1.564 | N/A | 6 | XMH2C455 |
| OG#18 | 6a | 80084Y | Omnigon Welland Aurum 2 | 30 | 60m | 3.504 | N/A | 6 | XMH2D445  XMH2D455 |
| OG#19 | 4a | 80087D | Omnigon Welland Aurum 2 Urostomy | 5 | 30m | 4.142 | N/A | 9 | XMH2UF419 |
| OG#20 | 4a | 80088E | Omnigon Welland Aurum 2 | 5 | 30m | 4.142 | N/A | 12 | XMH2F419 |
| OG#21 | 1b | 80093K | Omnigon Welland Aurum | 30 | 90m | 2.735 | N/A | 30 | XMHCL519  XMHCM519  XMHCS519  XMHCS522  XMHCS525  XMHCS532  XMHCS538  XMHCS544  XMHCS713 |
| OG#22 | 2a | 80094L | Omnigon Welland Aurum | 30 | 30m | 4.674 | N/A | 30 | XMHDM519  XMHDS519  XMHDS522  XMHDS525  XMHDS529  XMHDS532  XMHDS535  XMHDS538  XMHDS544  XMHDS713 |
| OG#23 | 3a | 80095M | Omnigon Welland Aurum | 10 | 60m | 4.674 | N/A | 18 | XMHUL519  XMHUM519 |

## Financial analysis

Substitute products are currently listed in the same subgroups at the same cost and maximum quantities. It is unlikely that there would be any budgetary impact for the SAS as a consequence of deleting the products.

## Recommendation

As these were administrative changes, these applications were considered by the Panel secretariat in line with the SAS *Application and Assessment Guidelines*. The Panel secretariat noted there are equivalent products remaining on the Schedule and recommended the deletion of the products.

Omnigon is to advise stoma associations, ostomates, stomal therapy nurses and the Australian Council of Stoma Associations of the deletion. A period of approximately 6 months from the date of the recommendation (12 November 2024) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.

## Context for Recommendation

The Panel secretariat, in accordance with the SAS Application and Assessment Guidelines, usually processes product deletions requested by the sponsor. This includes consideration of whether appropriate alternative products remain available on the SAS Schedule.

## Applicant’s Comment

# The applicant noted the recommendations.

1. Requires authorisation by an STN, nurse practitioner, registered nurse or registered medical practitioner. [↑](#footnote-ref-1)
2. No authority for an increase in the yearly allocation can be granted. [↑](#footnote-ref-2)