



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 restriction¹.

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.

¹ Requires authorisation by an STN, nurse practitioner, registered nurse or registered medical practitioner.



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 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 restriction².

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

² No authority for an increase in the yearly allocation can be granted.



Australian Government

Department of Health and Aged Care

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 XMHCDS113
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



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#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



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#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.

Addendum

The applicant requested to retain the following listings which it had requested be deleted. These listings will remain on the SAS Schedule and will not be deleted:



Application ID	Group ID	SAS Code	Brand Name	Pack Size	Max Qty	Unit Price	Price Premium	Total company codes	Company code/s to be retained
OG#15	1b	9781T	Omnigon Welland Flair Active	30	90m	2.735	N/A	28	XPLC732 XPLC735 XPLC744
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	XMH2D455
OG#21	1b	80093K	Omnigon Welland Aurum	30	90m	2.735	N/A	30	XMHCL519 XMHCS525 XMHCS532