



Stoma Product Assessment Panel Public Summary Documents Omnigon – 14 May 2024

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Omnigon Welland Night Drainage Bag with EasiFlo – OG#01MAY2024

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of the entire product range of the current listing of Omnigon Welland Night Drainage Bag with Easiflo (SAS Code 80073J) in subgroup 9(i) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued. The product, including one variant, is currently listed at a unit price of \$2.190 with a pack size of 5 and maximum monthly quantity of 5 units.

Variant to be deleted

Product Code	Description
ND700	Urostomy night drainage bag with Easiflo continuous flow device

Background

This product was first listed on the SAS Schedule on 1 April 2016.

Financial Analysis

Substitute products are currently listed in subgroup 9(i) of the SAS Schedule at the same cost and maximum monthly quantity. It is therefore unlikely that there would be any budgetary impact for the SAS as a consequence of deleting this product.

Recommendation

As this was an administrative change, this application was considered by the Stoma Product Assessment Panel (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 entire product range of Omnigon Welland Night Drainage Bag with Easiflo (SAS Code 80073J) listed in subgroup 9(i) of the SAS Schedule.

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 (14 May 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 recommendation.



Omnigon Stoma Support Belt– OG#02MAY2024

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of 2 variants from the current listing of Omnigon Stoma Support Belt (SAS Code 3858C) in subgroup 9(h) of the Stoma Appliance Scheme (SAS) Schedule, as they are being discontinued. The product, including 12 variants, is currently listed at a unit price of \$45.15, with a pack size of one and annual maximum quantity of 4 units.

Variants to be deleted

Product Code	Description
BOM110	RESTRICTED – stoma support belt, specially knitted Isoflex breathable fabric, no latex allergy, adjustable 15cm Velcro closure width, 20cm width, made to measure. R2
BOM210	RESTRICTED – stoma support belt, specially knitted Isoflex breathable fabric, no latex allergy, adjustable 15cm Velcro closure width, 26cm width, made to measure, R2

Background

The products were first listed on the SAS Schedule on 1 April 2011.

Financial Analysis

Substitute products are currently listed in subgroup 9(h) of the SAS Schedule at the same cost and maximum annual quantity. It is unlikely there would be any budgetary impact for the SAS as a consequence of deleting 2 variants of the product.

Recommendation

As this was an administrative change, this application was considered by the Stoma Product Assessment Panel (the Panel) secretariat in line with the *SAS Application and Assessment Guidelines*. The Panel secretariat noted there are equivalent products remaining on the SAS Schedule and recommended the deletion of 2 variants from the product range (12 variants) for Omnigon Stoma Support Belt (SAS Code 3858C) listed in subgroup 9(h) of the SAS Schedule.

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 (14 May 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 recommendation.



Omnigon Kool-Knit– OG#03MAY2024

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of 3 variants from the current listing of Omnigon Kool-Knit (SAS Code 9753H) in subgroup 9(h) of the Stoma Appliance Scheme (SAS) Schedule, as they are being discontinued. The product, including 33 variants, is currently listed at a unit price of \$45.15, with a pack size of one and annual maximum quantity of 4 units.

Variants to be deleted

Product Code	Description
KKB410N	RESTRICTED – Stoma and Hernia Support Belt, discreet specially designed for hot weather, beige breathable fabric, adjustable Velcro closure width, 17cm width, made to measure, R2
KKB510N	RESTRICTED – Stoma and Hernia Support Belt, discreet specially designed for hot weather, beige breathable fabric, adjustable Velcro closure width, 21.5cm width, made to measure, R2
KKB610N	RESTRICTED – Stoma and Hernia Support Belt, discreet specially designed for hot weather, beige breathable fabric, adjustable Velcro closure width, 26cm width, made to measure, R2

Background

The products were first listed on the SAS Schedule on 1 April 2011.

Financial Analysis

Substitute products are currently listed in subgroup 9(h) of the SAS Schedule at the same cost and maximum annual quantity. It is unlikely there would be any budgetary impact for the SAS as a consequence of deleting one variant of the product.

Recommendation

As this was an administrative change, this application was considered by the Stoma Product Assessment Panel (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 3 variants from the product range (33 variants) for Omnigon Kool-Knit (SAS Code 9753H) listed in subgroup 9(h) of the SAS Schedule.

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 (14 May 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 recommendation.



Omnigon Total Control – OG#04MAY2024

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of 3 variants from the current listing of Omnigon Total Control (SAS Code 9883E) in subgroup 9(h) of the Stoma Appliance Scheme (SAS) Schedule, as they are being discontinued. The product, including 18 variants, is currently listed at a unit price of \$45.15 with a pack size of one and annual maximum quantity of 4 units.

Variants to be deleted

Product Code	Description
TCB710	RESTRICTED – Stoma and Hernia Support Belt, universal Velcro adjustment, independent panel function, 15cm width, made to measure two panel, R2
TCB810	RESTRICTED – Stoma and Hernia Support Belt, universal Velcro adjustment, independent panel function, 22.5cm width, made to measure three panel, R2
TCB910	RESTRICTED – Stoma and Hernia Support Belt, universal velcro adjustment, independent panel function, 30cm width, made to measure four panel, R2

Background

The products were first listed on the SAS Schedule on 1 April 2011.

Financial Analysis

Substitute products are currently listed in subgroup 9(h) of the SAS Schedule at the same cost and maximum annual quantity. It is unlikely there would be any budgetary impact for the SAS as a consequence of deleting one variant of the product.

Recommendation

As this was an administrative change, this application was 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 3 variants from the product range (18 variants) for Omnigon Total Control (SAS Code 9883E) listed in subgroup 9(h) of the SAS Schedule.

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 (14 May 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 recommendation.



Omnigon Qufora Drainable Bed Bags – OG#05MAY2024

Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon, sought listing of Omnigon Qufora Drainable Bed Bags in subgroup 9(i) of the Stoma Appliance Scheme (SAS) Schedule. The product, including one variant, was proposed for listing at a unit price of \$2.190, with a pack size of 10 and a maximum monthly quantity of 5 units.

Comparator

The applicant nominated B. Braun Australia Pty Ltd Urimed Bag 2L (SAS Code 3951Y) as the comparator. The comparator product, with one variant, is currently listed in subgroup 9(i) of the SAS Schedule at the unit price of \$2.190, with a pack size of 10 and a maximum monthly quantity of 5 units.

Background

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

Clinical Analysis

The proposed product is an alternative for users requiring a drainable bed bag. The Panel noted that this was a new application to list a drainable bed bag for use with a urinary catheter.

Economic and Financial Analysis

The Panel noted that the listing of this new product at the same price and the same maximum quantity as currently listed products in the same subgroup is expected to result in the same monthly cost on the SAS. The Panel noted the product comes in a pack of 10 and recommended the product be supplied bi-monthly due to the current pack size and maximum quantity. The Panel suggested that the sponsor consider distributing the product to associations in a pack of 5.

Panel Recommendation

The Panel recommended that the Omnigon Qufora Drainable Bed Bags be listed in subgroup 9(i) of the SAS Schedule with one variant, at the unit price of \$2.190, with a pack size of 10 and a maximum monthly quantity of 5 units.

Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation 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. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.



Applicant's Comment

The applicant noted the recommendation.



Omnigon Qufora IrriSedo – OG#06MAY2024

Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon, sought listing of Omnigon Qufora IrriSedo in subgroup 8(b) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 13 variants, was proposed with the following prices, maximum quantities and comparator SAS codes.

Name	Description	Unit Price	Proposed Maximum Annual Quantity	Comparator SAS Code
Omnigon Qufora IrriSedo MiniGo	Omnigon Qufora IrriSedo MiniGo Base set - Kit includes: 1 x soft pump, 15 x cones	\$291.00	2	80267N
Omnigon Qufora IrriSedo MiniGo	Omnigon Qufora IrriSedo MiniGo Base set - Kit includes: 1 x soft pump, 30 x cones	\$533.50	2	80267N
Omnigon Qufora IrriSedo MiniGo	Omnigon Qufora IrriSedo MiniGo Flex Tubes Accessory set - Includes 15 MiniGo Flex tubes	\$170.00	9	80275B
Omnigon Qufora IrriSedo Flow	Omnigon Qufora IrriSedo Flow Start set - Kit includes: 1 x water bag with pump and water flow regulator, 15 x cones, 1 x hook, 1 x toilet bag for storage	\$383.15	2	80267N
Omnigon Qufora IrriSedo Flow	Omnigon Qufora IrriSedo Flow Cone set - Includes: 15 x cones	\$360.00	3	80273X
Omnigon Qufora IrriSedo Flow	Omnigon Qufora IrriSedo Flow Base set - Kit includes: 1 x water bag with pump and water flow regulator, 15 x cones	\$383.15	9	80275B
Omnigon Qufora IrriSedo Flow	Omnigon Qufora IrriSedo Flow Base set - Kit includes: 1 x water bag with pump and water flow regulator, 30 x cones	\$678.03	9	80275B
Omnigon Qufora IrriSedo Klick	Omnigon Qufora IrriSedo Klick Base set - Kit includes: 1 x control unit, 1 x water bag, 2 x coated balloon catheters, 1 x	\$234.75	2	80267N



Name	Description	Unit Price	Proposed Maximum Annual Quantity	Comparator SAS Code
	tube, 1 x hook, 1 x toilet bag for storage			
Omnigon Qufora IrriSedo Klick	Omnigon Qufora IrriSedo Klick Base set - Kit includes: 1 x control unit, 1 x water bag, 15 x coated balloon catheters, 1 x tube, 1 x hook, 1 x toilet bag for storage	\$531.23	2	80267N
Omnigon Qufora IrriSedo Klick	Omnigon Qufora IrriSedo Klick Catheter set - Kit includes: 15 x coated balloon catheters	\$361.05	3	80273X
Omnigon Qufora IrriSedo Klick	Omnigon Qufora IrriSedo Klick Accessory set - Kit includes: 1 x water bag, 15 x coated balloon catheters, 1 x tube	\$396.53	9	80275B
Omnigon Qufora IrriSedo Klick	Omnigon Qufora IrriSedo Klick Accessory set - Kit includes: 1 x water bag, 30 x coated balloon catheters, 1 x tube	\$688.70	9	80275B
Omnigon Qufora IrriSedo Klick	Omnigon Qufora IrriSedo Klick Tube - Kit includes: 1 x Klick tube	\$28.00	4	80275B

Comparator

The applicant nominated Coloplast Peristeen Plus as the comparator. The comparator SAS codes are listed in the above and below tables. The products are currently listed in subgroup 8(b) of the SAS Schedule at the following unit prices and maximum monthly quantities.

Name and SAS Code	Description	Unit Price	Maximum Annual Quantity
Coloplast Peristeen Plus system – cone - 80267N	RESTRICTED Includes the following: 1 x screw top including lid to connect control unit to water bag, 1 x 1L water bag with temperature indicator, 1 x control unit, 1 x tube, 2 x coated rectal cone catheters, 2 x straps to secure the system while being used, 1 x toiletry bag for system storage., R4	234.75	2a



Name and SAS Code	Description	Unit Price	Maximum Annual Quantity
Coloplast Peristeen Plus system – regular - 80267N	RESTRICTED Includes the following: 1 x screw top including lid to connect control unit to water bag, 1 x 1L water bag with temperature indicator, 1 x control unit, 1 x tube, 2 x coated regular rectal balloon catheters, 2 x straps to secure the system while being used, 1 x toiletry bag for system storage., R4	234.75	2a
Coloplast Peristeen Plus system – small - 80267N	RESTRICTED Includes the following: 1 x screw top including lid to connect control unit to water bag, 1 x 1L water bag with temperature indicator, 1 x control unit, 1 x tube, 2 x coated small rectal balloon catheters, 2 x straps to secure the system while being used, 1 x toiletry bag for system storage., R4	234.75	2a
Coloplast Peristeen Plus catheters – cone - 80273X	RESTRICTED Includes the following: 15 x coated rectal cone catheters., R4	361.05	3a
Coloplast Peristeen Plus catheters – regular - 80273X	RESTRICTED Includes the following: 15 x coated regular balloon catheters, R4	361.05	3a
Coloplast Peristeen Plus catheters – small - 80273X	RESTRICTED Includes the following: 15 x coated small balloon catheters, R4	361.05	3a
Coloplast Peristeen Plus accessory unit – cone - 80275B	RESTRICTED Includes the following: 1 x water bag, 15 x coated rectal cone catheters., R4	396.53	9a
Coloplast Peristeen Plus accessory unit – regular - 80275B	RESTRICTED Includes the following: 1 x water bag, 15 coated regular rectal balloon catheters., R4	396.53	9a
Coloplast Peristeen Plus accessory unit – small - 80275B	RESTRICTED Includes the following: 1 x water bag, 15 x coated small rectal balloon catheters., R4	396.53	9a



Background

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

Clinical Analysis

The proposed product is an alternative for users requiring a transanal irrigation (TAI) kit. The product sponsor sought consideration for listing of the product for use in children aged 3 to 17.

The submission provided evidence including 4 clinical studies for the use of TAI in the following patient groups: paediatric patients with Spina Bifida, TAI in adults, patients with lower motor neurone spinal cord injury, and adults with chronic constipation. The Panel noted that the clinical evidence provided by the sponsor did not support the use of the product in patients with neo-anus openings or stomas, in line with the eligibility criteria for people who can access the SAS, or in the proposed population range of 3-17 years of age. The product sample provided by the product sponsor appeared to be in an adult size, which compelled the Panel to question the safety of use of the product in children or young adolescents.

Economic and Financial Analysis

The product sponsor indicated a similar or lower financial impact compared to the comparator in their submission directly referencing the Qufora IrriSedo MiniGo and Flow as lower cost options compared to the balloon catheter of the comparator.

The Panel noted the total quantity for the catheter products submitted by Omnigon is more than double the total quantity of the comparator.

The product sponsor indicated the use of the Qmningon Qufora IrriSedo products on the SAS Schedule would reduce wastage and improve compliance providing a cost neutral benefit to the SAS, however this is unclear in the evidence provided. The submission included a financial assessment of the Omnigon Qufora IrriSedo on the SAS Schedule over a period of 4 years. The Panel questioned the financial estimates provided in the submission and noted that it is unclear what assumptions went into the estimated total costs across all products in year one.

The Panel noted that it is unclear from the evidence provided whether the product requested for listing would result in the same cost to the SAS as the comparator.

Panel Recommendation

The Panel rejected the application for the Omnigon Qufora IrriSedo with 13 variants in subgroup 8(b) of the SAS. The Panel noted that it would welcome a reapplication from the product sponsor at a future meeting, including evidence to support the safe use in a population of 3 to 17 years with an appropriate sample size for the age range, and evidence regarding clinical effectiveness in patients that are eligible to access the SAS i.e. people with



a stoma or neo-anus opening. Further clarification on the quantity of catheter products required would also be necessary. If deemed suitable for listing, the product would be subject to restriction.

Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation 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. The Panel is an advisory committee and as such 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 Dot 1 Piece Soft Convex High Output – OG#07MAY2024

Proposed Variation on the Stoma Appliance Scheme

The applicant, Omnigon, sought a change in the company code of the current listing of the Omnigon Eakin Dot 1 Piece Soft Convex High Output (SAS Code 80229N) in subgroup 11(a) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 2 variants, is currently listed at a unit price of \$22.33, with a pack size of 10 and a maximum monthly quantity of 20 units.

Variations to listings

Product Name	Current Company Code	New Company Code
Omnigon Eakin Dot 1 Piece Soft Convex High Output	841000NF	851000NF
Omnigon Eakin Dot 1 Piece Soft Convex High Output	841001NF	851001NF

Background

This product was first listed on the SAS Schedule on 1 November 2011.

Financial Analysis

The variations do not include any changes to the price or maximum quantity of the current product range and are unlikely to have a budgetary impact for the SAS.

Recommendation

As this was an administrative change, this application was considered by the Stoma Product Assessment Panel (the Panel) secretariat in line with the *SAS Application and Assessment Guidelines*. The Panel secretariat recommended the variation to the company code for the current product range (2 variants) for Omnigon Eakin Dot 1 Piece Soft Convex High Output (SAS Code 80229N) listed in subgroup 11(a) of the SAS Schedule. The Panel noted the secretariat's recommendation at the May 2024 meeting.

Context for Recommendation

The Panel secretariat, in accordance with the *SAS Application and Assessment Guidelines*, can process variations to products where there is no change to classification, pricing, maximum quantity or composition. All recommendations are subject to Government approval.

Applicant's Comment

The applicant noted the recommendation.