

Value Dossier

SenSura®

Value Story

Leakage and skin complications are large concerns for stoma users, demanding an appliance that provides them with the feeling of an appliance that always works.

The full range of SenSura® appliances, with the double layer adhesive, is developed to provide security and deliver less leakage and skin complications. SenSura® appliances are unique solution for stoma users and healthcare authorities, by reducing leakage and by decreasing total cost of stoma care.

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Value Summary

Improved security

Need for secure stoma appliances

Feeling of security is a large concern for people with ostomies and there is a need for appliances that are able to provide feeling of security, less leakage and less peristomal skin complications.

Currently, there is no ostomy appliance available, besides SenSura, with a double layer adhesive that provides security in attachment to the body and ability to improve the condition of the peristomal skin.

Double layer adhesive

The SenSura range features a unique double layer adhesive, which is developed to secure fit to the peristomal skin and improve security

- SenSura has the only double layer adhesive on the market
- SenSura decreases leakage and peristomal skin complications
- SenSura decreases the use of accessories
- SenSura increases quality of life

"I clearly feel that removal of the adhesive is much easier. It was more comfortable and not so irritating to the skin" – Testimonial from SenSura user

Cost-effectiveness

SenSura provides the ability to lower total costs of stoma care

1. Unmet Need

1.1. *Secure appliances that reduces stoma related complications*

People with stomas experience problems with the security of the product in relations to problems with leakages and skin complications. A stoma appliance with the ability to deliver more security and ability to decrease the level of both leakages and severity of peristomal skin complication was needed.

The SenSura range offers a unique, double layer adhesive that provides a better seal to the body, providing the ability to lower leakage and decrease the severity of peristomal skin complications.

1.2. *Current Standard Treatment*

The available appliances are able to prevent some degree of leakage and deliver a feeling of security, but a better security and even more decrease of leakage and severity of peristomal skin complications is needed.

A global study (DialogueStudy) involving 3017 patients demonstrated that when ostomy appliance users using SenSura products instead of their regular standard treatment product, a positive effect on peristomal skin complications was observed. There was a decrease in frequency of peristomal skin complications and the skin was assessed using the Ostomy Skin Tool (measuring DET-score) with a reduction in the DET-score from 2.5 to 1.6 during the study⁽¹⁾.

This shows that there is a need for appliances as those in the SenSura range, and that it is possible that SenSura provides better feeling of security and decreases both the level of leakage and severity of peristomal skin complications.

2. Value Argumentation

2.1. *SenSura*

Products from the SenSura range are developed in close cooperation with healthcare professionals and end-users, to create products which met the need for all-round security and wearing comfort.

To improve security, the baseplates in SenSura range features a unique double layer technology. The first layer is the protection layer that is made of strong adhesive material, keeping a secure seal between the stoma and the peristomal skin, protecting the peristomal skin from stoma effluent. The second layer is the skin care layer, which serves to absorb excess moisture and thereby keep the peristomal skin healthy and ensuring consistent adhesion to the skin.



Protection layer



Skin care layer

The SenSura product range comprises many different devices for various types of ostomies. In the SenSura range there are products for users with colostomies, ileostomies and urostomies, as well as there are products for 1 piece users as well as 2 piece users. Both 1 and 2 piece products are available with flat baseplates and a light convex baseplate. For the 2 piece products there are two coupling technologies available, a mechanical and an adhesive named SenSura Click and SenSura Flex.

SenSura product range:

- SenSura 1 piece
- SenSura Click (2 piece)
- SenSura Flex (2 piece)



SenSura 1 piece



SenSura Click



SenSura Flex

We recommend SenSura to all users who are currently using 1 or 2 piece ostomy devices with traditional adhesives.

2.2. Value Drivers

Unmet need

For ostomates, the feeling of security with the stoma appliance is very important. It is important to have adhesive properties that secure tight fit to the peristomal skin, but also helps to decrease the severity of peristomal skin complications. The adhesive technology of the SenSura range is a unique solution and performs well regarding these aspects.

Double layer adhesive

The double layer adhesive used with SenSura is a unique solution, which offers various advantages for the users. The outer protection layer provides secure adhesion to the skin and the inner skin care layer provides the ability to absorb excess moisture, keeping the skin healthy and optimising the adhesion ability.

The SenSura product range is the only stoma products with a double layer adhesive, making it a unique option.

Reduces leakage and peristomal skin complications

SenSura products are better performing than best standard of care appliances shown in a global study. Use of SenSura instead of standard of care appliances showed a decrease in severeness of peristomal skin complications measured by use of the Ostomy Skin Tool. The study also showed reductions the number of participants experiencing leakage, meaning that use of SenSura appliances reduces leakage.⁽²⁾

Use of SenSura decreases amount of accessories used

A large proportion of stoma users use accessories to increase fit to the peristomal skin, but also to reduce problem originating from leakage. In the DialogueStudy, it was shown that SenSura reduces the amount of accessories.⁽³⁾

SenSura reduces costs

Our health economic model shows that, if the SenSura range is introduced, the total cost of stoma care will be lowered.

SenSura increases quality of life

Quality of life for stoma patients depends on security, protection of the skin and discretion. Skin problems result in a poorer quality of life^(4; 5) and additional costs due to follow-up treatment⁽⁶⁾. SenSura significantly increases quality of life, shown in clinical studies.⁽³⁾

Improved filter technology

The filter used in SenSura bags are better than competitor filters, showed by studies investigating the performance of the filters. The SenSura filter showed better at ballooning, but also a better performance in regards to odor control.^(7; 8)

Patient preference

In competition with comparable stoma appliances, SenSura is the one preferred by the users. In several studies of SenSura and competitor products, SenSura was preferred, with the study participants preferring it 75% of the cases and upwards to 98%. All studies showed significant difference in regards to this question.^(7; 8; 9; 10; 11)

Testimonials

End-users:

"I will recommend Sensura to everyone who needs an ostomy appliance. Very flexible and skin friendly. I am very satisfied with SenSura!"

"I did not feel my skin was quite as exposed as with my usual product - perhaps I could avoid carrying skin preparation around with me in the handbag all the time"

"I clearly feel that removal of the adhesive is much easier. It was more comfortable and not so irritating to the skin"

Differentiation in procurement

- SenSura has the only double layer adhesive on the market
- SenSura reduces leakage and severity of peristomal skin complications
- SenSura reduces the use of accessories
- Total costs of stoma care is reduced when SenSura is introduced

Contact Market Access for support in your market

Note on wear-time

The value of SenSura has previously been promoted by marginal differences in wear time. However the value story described in this value dossier is more potent. To simplify communication on the value of SenSura, focus on wear time has not been prioritized. The difference in wear times are also questionable and wear time is probably more influenced by patient preference and output patterns than product performance.

3. Evidence

3.1. Clinical Evidence

DK 1750S – The DialogueStudy

A global study (DialogueStudy) involving 3017 patients with an ostomy, demonstrated that when ostomy appliance users received 6-8 weeks treatment with our current SenSura range there was a positive effect on peristomal skin complications. The skin was assessed using the Ostomy Skin Tool (DET-score) with a reduction in DET-score from 2.5 to 1.6 during the study and the study also showed a reduction in frequency of peristomal skin complications. The results showed that a combination of study effect and SenSura, improves the peristomal skin conditions, but further improvement in peristomal skin complications are possible. The Dialogue Study also investigated the improvement in quality of life experienced by the users. This was done by using the Stoma-QoL questionnaire and showed a significant increase in quality of life after the intervention.⁽¹⁾ Furthermore, it was shown that the level leakage decreased over the course of the study and that the use of accessories also decreased when using SenSura.⁽³⁾

A Dialogue Study publication indicates that the effect seen in the study is study effect, SenSura and evidence based nursing in combination. Evidence based nursing was not required in the study design and can therefore not be specified as a cause for the improvement. However, in a non blinded, uncontrolled study there are study effects and it can include a higher level of nursing, but this should not be accounted as a key reason for the improvement.

A sub-analysis performed on the dataset from the Dialogue Study have shown, that the baseline DET-score was not significantly different between those who have had adequate access to nursing and those without adequate access, meaning that the positive effect seen in the Dialogue study is mainly caused by a combination of study effect and the use of SenSura appliances.⁽²⁾

Ostomy Skin Tool: <http://www.coloplast.com/ostomycare/topics/educationtools/theostomyskintool/>

Stoma-QoL: <http://www.coloplast.com/ostomycare/topics/educationtools/stoma-qol/>

DK1090S study

Open, randomised, comparative crossover multi-centre study of SenSura one-piece closed versus Dansac Nova 1. The study was based on 68 one-piece users and showed a significant preference towards the SenSura appliance. SenSura was preferred by 85% and 94% rated the security of the appliance very good or good versus 76% for the reference appliance. The study also showed that the filter performed better than that of the reference product in regards to ballooning, where 27% of all reference appliances showed ballooning, compared to 7% for SenSura.⁽⁷⁾

DK1450S study

Open, randomised, comparative crossover multi-centre study of SenSura one-piece closed versus Hollister Moderma Flex. The study was based on 69 colostomists and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 78% and performed significantly better in regards to ballooning, with ballooning occurring with 23% of the reference appliance versus 6% for SenSura.⁽⁸⁾

DK151OS study

Open, randomised, comparative crossover multi-centre study of SenSura one-piece open versus Hollister Modema Flex with Lock'n Roll. The study was based on 64 one-piece users and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 79% and the feeling of security was rated good or very good by the users in 80% of the cases for SenSura and 70 % for the reference appliance.⁽⁹⁾

DK153OS study

Open, randomised, comparative crossover multi-centre study of SenSura one-piece open versus ConvaTec Esteem with InvisiClose. The study was based on 59 ileostomists and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 75% and the appliance performed better in regards to filter performance where odour problems were experienced with 25% of the reference appliance versus 7% with SenSura. Wear-time with the SenSura appliance was significantly higher with 26.9 hours versus 22.8 hours for the reference appliance.⁽⁸⁾

DK163OS study

Open, randomised, comparative crossover multi-centre study of SenSura one-piece open versus Hollister Premier one-piece with Lock'n Roll. The study was based on 36 colostomists and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 86% and the overall performance of the appliances was rated as very good or good by 67% for SenSura and 32% for the reference appliance.⁽¹⁰⁾

DK167OS study

Open, randomised, comparative crossover multi-centre study of SenSura two-piece closed versus ConvaTec Combihesive Natura with Stomahesive Skin Barrier and Natura Closed bag. The study was based on 63 colostomists and showed that SenSura had a better overall performance with 87% rating it very good or good compared to only 13% for the reference appliance. There was also a significant higher preference for SenSura with 98% of the users preferring it over the reference appliance.⁽¹¹⁾

DK168OS study

Open, randomised, comparative crossover multi-centre study of SenSura two-piece open convex versus Hollister Conform 2 FlexWear convex and Conform 2 open bag. The study was based on 59 ileostomists and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 96% and the condition of the peristomal skin was also significantly improved after use of the SenSura appliance.⁽¹²⁾

DK173OS study

Open, randomised, comparative crossover multi-centre study of SenSura Flex closed versus ConvaTec Esteem Synergy 2 piece closed. The study was based on 46 colostomists and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 74% and there was also a significant difference in the feeling of security and ability of the filter to reduce odour.⁽¹³⁾

DK189OS study

Open, randomised, comparative crossover study of SenSura Uro 2 piece versus ConvaTec Combihesive Natura. The study was based on 27 urostomists and showed a significant difference in preference towards the SenSura appliance. SenSura was preferred by 84% of the participants.⁽¹⁴⁾

Summary of Clinical Evidence

SenSura has been clinically assessed, evaluated, and has shown superior performance in some of the key aspects of stoma care, indicating that SenSura should be the preferred product compared to best standard of care.

Clinical studies demonstrate that use of Sensura is deemed acceptable and does not pose an increased risk for the user.

3.2. Health Economic Evidence

Health Economic Model

To prove total decrease in costs when using SenSura, a health economic model has been developed. The model is based on the DET-score measured with the Ostomy Skin Tool and calculates the cost of treating the peristomal complications and costs of ostomy products and accessories. The current version of the model is based on data obtained from the Dialogue Study and calculates the cost for a 7-week period.⁽¹⁵⁾

Basics of the model

The core of the health economic model transforms the DET-scores to monetary units, meaning that cost data is assigned to the DET-data applied to the model. In order to do so, a consolidation of the scoring of DET-scores have been developed as well as global treatment algorithms for the consolidated groups have been established. The DET-status can normally range from 0-15 for each of the 5 causes of skin complications seen in the grey boxes in Figure 1. In order to make the model more simple and transparent, the scores from 0-15 were consolidated to three levels of severity, Mild, Moderate and Severe, for each of the 5 cause groups as seen in Figure 1.⁽¹⁵⁾

Irritant contact dermatitis	Mild	Moderate	Severe
Allergic dermatitis	Mild	Moderate	Severe
Mechanical trauma	Mild	Moderate	Severe
Disease related	Mild	Moderate	Severe
Infection related	Mild	Moderate	Severe

Figure 1 shows the core of the model. The DET-score is applied to the 15 consolidated groups for which cost data can be applied⁽¹⁵⁾

For each of the 15 severity groups, global treatment algorithms have been developed. Stoma care nurses were asked to give their view on the treatments available, and the probability of a user with such condition receiving the treatment, for each of the 15 groups. The result of this can be found in Table 1, where an example for moderate irritant contact dermatitis is shown. All users with moderate irritant contact dermatitis will be consulted by a stoma care nurse, 51% will be consulted a 2nd time and 15% will be consulted a 3rd time. On top of that 6% will also receive topical treatment.⁽¹⁵⁾

Moderate irritant contact dermatitis	
100 %	1 st SCN consultation
51 %	2 nd SCN consultation
15 %	3 rd SCN consultation
6 %	Topical corticosteroids

Table 1 treatment algorithm for moderate irritant contact dermatitis, showing the possible treatments and probability⁽¹⁵⁾

Treatment algorithms, like the one in Table 1 are available for all 15 severity categories. By having developed these algorithms, it is possible to apply costs to every possible DET-score, meaning that nursing costs, medical treatment costs etc. can be calculated for each of the 15 categories, subsequently meaning that a total mean cost of treating a larger group of ostomates with skin complications can be calculated.⁽¹⁵⁾

Example of use: Sweden

When Swedish cost-data are applied to the model, the result shows that SenSura is able to lower total costs of stoma care over a 7-week period versus best standard of care, when priced at the pricing level it had in 2011. The results shows, that the costs of appliances when using SenSura is higher than standard care, but the difference is made up from less use of accessories and fewer costs for treating peristomal skin complications (PSC).

	Appliances	Accessories	PSC	Total
SenSura	3,410.40 SEK	250.03 SEK	550.84 SEK	4,211.28 SEK
Standard care	3,071.12 SEK	349.57 SEK	922.35 SEK	4,343.04 SEK
Difference				-131.77 SEK

Table 2 is showing the results of the health economic model, showing that SenSura is able to lower total costs of stoma care in Sweden when compared to best standard of care. (PSC, peristomal skin complications)

Please contact Market Access for a country specific analysis that is adapted to your market, before referring to the health economic model.

Willingness-To-Pay (WTP)

A study including 254 ostomy end-users in Sweden, investigated the WTP for new ostomy appliances. The study measures the end-users preference for potential improvements in features. The features investigated were various levels of performance of filter, flexibility and leakage. Ultimately, the researcher were able to calculate WTP per level of performance and showing a WTP of SEK408 per month over their usual product, for a fictive product delivering 24 hour lifetime, 0 episodes of leakage per month and a large improvement in flexibility.⁽¹⁶⁾

Using the WTP-data from the study shows that the WTP for a product with features equal to those of SenSura is positive. SenSura have the flex-zones and might be regarded as providing a small improvement in flexibility. Filter data shows, that the filter used in SenSura can last 12 hours and data for leakage shows that SenSura would fit in the second-best category for leakage. This means, using WTP data from the study, that the WTP for a product with the abilities of SenSura Mio is SEK115 per month over their usual product.

Please contact Market Access for support on how WTP can be utilized in your market.

3.3. Other evidence

Testimonials

Testimonials from patients and health care professionals are continuously collected and can be requested from Market Access

4. References

Please see Market Access on Connect, if a copy of a reference is needed, or contact Market Access

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