


125 mm

62,5 mm 62,5 mm

40 mm TEXT FREE AREA



Powder for oral solution

Ingredients: Macrogol, Sucralose

Packs: Senosoft is available in the following pack sizes:
- 10 single-dose sachets (10g per sachet)
- 20 single-dose sachets (10g per sachet)

How it works: Senosoft contains Macrogol 4000, which is an osmotic laxative that promotes re-hydration and softens the stools, helping to make them easier to pass. It is not absorbed or metabolised in the intestinal tract.

Indications: Symptomatic treatment of constipation.

How to take:
For adults and children over 12 years of age 1-2 sachets per day. May be increased up to 4 sachets per day if required.

Dosage should be increased or reduced, according to the individual response to the treatment, in order to promote regular bowel movements. Maximum dose should not exceed 4 sachets per day.

Pour the powder in water or in other liquids (125 ml for each sachet), stirring for 30 seconds or until dissolved, and drink it immediately after. In case of minimum dose intake (1 sachet daily), it is recommended to take the product in the morning. For higher doses, split the intake between morning and evening.

Works within 24-72 hours. If you are still not feeling better after 7 days of treatment, it is recommended to consult your doctor.

How to store:
Keep out of the reach and sight of children. Store in a dry and cool place, protected from light and away from heat sources. The expiry date refers to the product stored correctly, in undamaged package.

TEXT FREE AREA

240 mm

(IFU1_11/19r0_03/20)
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125 mm

Warnings:
Do not use the product after the expiry date which is stated on the package. The use in children must be under direct adult supervision. Do not use if the package has been opened or damaged. Suitable for pregnant and breastfeeding women, consultation with a doctor is advised before use. The product may reduce the gastrointestinal transit time and thus reduce the absorption of orally administered drugs. Consult a doctor before using the product if taking any other treatment by mouth. In any case, the interval between oral doses of Senosoft and other oral drugs should be at least 2 hours. In case of adverse reactions stop using the product and consult your doctor.



CONTRAINDICATIONS
Do not use Senosoft in case of:
- Hypersensitivity to one or more components
- Intestinal perforation, obstruction or stenosis
- Paralytic ileus
- Severe inflammatory disease of the intestinal tract (e.g. ulcerative colitis, Crohn's disease, toxic megacolon)

Laxatives are contraindicated in presence of acute abdominal pain, abdominal pain of unknown origin, nausea and vomiting, rectal bleeding of unknown origin or in case of severe dehydration.


Potential side effects:
Reactions related to the gastrointestinal tract may occur (abdominal pain, flatulence, abdominal distension, nausea, faecal incontinence). Diarrhoea is a consequence of overdose intake of Senosoft and it responds to dose reduction. Rarely, hypersensitivity reactions have been reported (skin rash), as a result of the use of products containing macrogol. In this case, discontinue the treatment and consult the doctor.

 **Biofarma – Via Castelliere 2 – Mereto di Tomba (UD) – Italy**

Distributed by: Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS. Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

Medical Device
 0373 

Date of last revision: **November 2019** (IFU1_11/19r0_03/20)

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RB Artwork and Print Specification

Trident Reference No:	RB406061
ZEN Ref:	TR1764682
Action:	F
Brand:	Senokot
Category:	Senosoft
Segment Group:	Adult
Segment:	Various
Pack Size:	10/20Sachets
Market/Country:	UK and Ireland
Date:	13/03/20

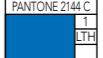

RBH Contact: Fran Marks

Artwork Type: **BW Commercial**

Component Code (2D if applicable):	3132156
2 nd Component Code (if applicable):	N/A
Parent Technical Packaging Specification:	D8369207
Finished Goods Code:	3132009 3132010
Supply Point:	Biofarma
3rd Party Code:	(IFU1_11/19r0_03/20)
Pharmacode No/NE:	N/A
Edgemark Position:	N/A

CAD Cam Ref:	Lft-D8369207-125x240mm
Printer:	Palladio Industrie Grafiche(Vicenza, Italy)
Substrate:	Paper

Technical & Non Printing Items	
 Cutter	 Cutter 2 (if applicable)
 Guides	 Guides 2 (if applicable)

Colours (Leaflet)	
	

 	
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BARCODE INFO

Barcode Type:	N/A
Barcode Number:	N/A
Magnification:	N/A
Truncated By:	N/A
Full Height:	N/A
Bar Height (Smallest Bar):	N/A
BWR:	N/A
Encoded Data:	N/A



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UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

STUDIO USE ONLY	Ryan Reilly	v2.0
Sm•Art check results:	G=2; O=0; R=0; - RR - 13/03/20 13:09:08	

CUSTOMER INFO:
Minimum Point Size = 9.00pt



Production line			
Manufacturing site			
Pack Tech approver	1st	2nd	
Date			
Check Criteria	Details Et Comments	Checks	
Approvals		1st	2nd
Market Approval			
Regulatory Approval			
3rd Party Approval			
Technical Drawing/ Cutter ref no. Et PPI component code			
PPI component code number/s correct on artwork?			
PPI component code number/s in correct position on artwork?			
Correct drawing for the production line?			
Profile shape Et dimensions			
Graphics layout/orientation			
Unwind diagram (PPTD1022/1-20)			
Printable areas/bleed			
Varnish free areas			
Variable coding position Et dimensions			
Varnish and print requirements			
Pre-printed headers (alignment and suitability)			
Embossing, Braille Et Foil Blocking			
Separations on artwork			
Alignment within cutter			
Braille structure			
Verification Code Type; Pharma Code / 2D / OCV			
Bar sequence and/or number correct on artwork			
Bar sequence and/or number in correct position on artwork?			
Size (height, width, spacing, font)			
Direction of read			
Light margins and print free areas			
Colour			
Repeat distance (reeled material)			
Cross check related docs ie BOM			
Bar code Type; EAN, ITF, Code39, etc			
Magnification / width and height			
Colour (e.g. black print on white background)			
Light margins Et indicators			
Bearer bars Et H gauges (if required)			
Symbol grade (Pass = A,B,C; Action = D,F)			
Bar code number (human readable)			
Bar code number (encoded Et hidden data)			
Confirm bar code number from source			
Cross check related docs (JDE/PID)			
Photo-electric cell mark / edge marks			
Present Et per Tech drawing?			
Correct pitch?			
Additional markings			
e-mark, recycle logo etc			
Legend box (RB specification)			
Correct component code			
Correct D spec / has cutter changed?			
Correct printer / has printer changed?			
Correct Substrate			
A/W is set up appropriately for this substrate			
Edge mark details			
Pharmacode details			
Colours Et print process			
Varnish			
Barcode information			
General details are correct			
Pass / Fail comments and Signature			
By approving the artwork referenced within this form I authorise it for release to the print supplier			
Additional Comments			

RB Artwork and Print Specification

Trident Reference No: RB406061
 ZEN Ref: **TR1764682**
 Action: **F**
 Brand: Senokot
 Category: Senosoft
 Segment Group: Adult
 Segment: Various
 Pack Size: 10/20Sachets
 Market/Country: UK and Ireland
 Date: 13/03/20

RBH Contact: Fran Marks

Artwork Type: **BW Commercial**

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 2nd Component Code (if applicable): **N/A**
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 Finished Goods Code: **3132009 3132010**
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 3rd Party Code: (IFU1_11/19-0_03/20)
 Pharmacode No/NE: N/A
 Edgemark Position: N/A

CAD Cam Ref: Lft-D8369207-125x240mm
 Printer: Palazzo Industrie Grafiche(Vicenza, Italy)
 Substrate: Paper

Technical & Non Printing Items
 Cutter Cutter 2 (if applicable)
 Guides Guides 2 (if applicable)

Colours (Leaflet)
 PANTONE 2144 C

BARCODE INFO

Barcode Type: N/A
 Barcode Number: N/A
 Magnification: N/A
 Truncated By: N/A
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 Bar Height (Smallest Bar): N/A
 BWR: N/A
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