

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

Anusol Suppositories

COMPOSITION:

Each suppository contains:

Bismuth Subgallate	59,0 mg
Bismuth Oxide	24,0 mg
Zinc Oxide	296,0 mg

PHARMACOLOGICAL CLASSIFICATION:

A 11.8 Suppositories and anal ointments.

PHARMACOLOGICAL ACTION:

Anusol Suppositories lubricate and soothe, and help to reduce the oedema and pain of irritated anorectal membranes.

INDICATIONS:

Anusol Suppositories soothe the pain and irritation of haemorrhoids (piles), and other related anorectal conditions.

CONTRA-INDICATIONS:

Serious rectal pathology. Haemorrhoids and other inflammatory conditions of the rectum are sometimes of a serious nature. In cases of rectal bleeding, or persistence of the condition, consult your doctor.

Known hypersensitivity to any of the ingredients.

WARNINGS:

As with all bismuth-containing preparations, neurotoxicity may occur with prolonged or excessive use.

DOSAGE AND DIRECTIONS FOR USE:

Not to be taken orally.

The area around the anal opening should be cleansed with soap and warm water, then dried carefully by patting (not rubbing) with soft toilet tissue or cotton wool before medication is used.

Adults:

Remove plastic cover and insert one suppository in the morning, one at bedtime and one after every evacuation or as directed by the physician.

1. Tear along the perforation to remove one suppository from the strip (see figure 1 below).

SKEDULERINGSSTATUS: S0

EIENDOMSNAAM (EN DOSEERVORM):

Anusol Septille

SAMESTELLING:

Elke setpil bevat:	
Bismutsubgallaat	59,0 mg
Bismutoksied	24,0 mg
Sinkoksied	296,0 mg

FARMAKOLOGIESE KLASSIFIKASIE:

A 11.8 Setpille en anale salwe

FARMAKOLOGIESE WERKING:

Anusol Setpille smeer en streef, en help om die edeem en pyn van geïrriteerde anorektale slymvliese te verminder.

INDIKASIES:

Anusol Setpille streef die pyn en irritasie van hemoroïede (aambeie) en ander verwante anorektale toestande.

KONTRA-INDIKASIES:

Ernstige rektale patologie. Hemoroïede en ander ontstekingstoestande van die rektum is soms van 'n ernstige aard. Raadpleeg u dokter in gevalle van rektale bloeding of indien die toestand voortduur. Bekende hipersensitiwiteit teenoor enige van die bestanddele.

WAARSKUWING:

Net soos in die geval van alle bismutbevattende preparate, mag neurotoksisiteit voorkom wanneer dit langdurig of oormatig gebruik word.

DOSIS EN GEBRUIKSAANWYSINGS:

Moet nie mondelings geneem word nie.

Die gebied om die anale opening behoort met seep en warm water gereinig te word en dan versigtig met sagte sneespapier of watte drooggetik te word voordat medikasie gebruik word. Die gebied moet egter nie gevryf word nie.

Volwassenes:

Verwyder plastiese omhulsel en plaas een setpil in soggens, een saans en een na elke ontlasting, of volgens voorskrif van die geneesheer.

1. Skeur al langs die perforasie om een setpil uit die strokie te verwyder (sien skets 1 hieronder).

- Grasp the two halves of the plastic cover firmly, holding between the thumb and forefinger of each hand (as indicated in figure 2 below). Gently pull apart to fully expose the suppository.
- Remove the suppository, and insert as deeply into the anus as possible.

The suppositories are specially shaped for easy insertion into the anus. You may find insertion of the suppositories easier if you place one foot on a chair or lie on your side with one leg drawn up as high as possible under the chin.



Figure 1



Figure 2

Children: Not recommended.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Hypersensitivity reactions may occur. Use should be discontinued if redness, irritation, swelling or pain persists or increases.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

White to off-white, bullet-shaped suppositories with a characteristic balsamic odour.

PRESENTATION:

A pack containing two PVC blisters of 6 suppositories each (12 suppositories).

STORAGE INSTRUCTIONS:

Keep in a cool (at or below 25 °C), dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/11.8/0515

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

MDI Healthcare CC
374 Anderson Street
Menlo Park, 0081
South Africa

- Hou die twee helftes van die plastiese omhulsel styf tussen die duime en wysvingers van albei hande vas (soos aangedui in skets 2 hieronder). Trek versigtig uitmekaar totdat die setpil sigbaar is.
- Verwyder die setpil en steek dit so diep as moontlik in die anus op.

Die setpille is spesifiek ontwerp sodat hulle maklik in die anus opgesteek kan word. U mag dit makliker vind om die setpille in te steek as u een voet op 'n stoel rus of op u sy lê en een been so hoog as moontlik onder u ken optrek.



Skets 1



Skets 2

Kinders: Nie aanbeveel nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Oorgevoeligheidsreaksies mag voorkom. Gebruik behoort gestaak te word indien rooiheid, irritasie, swelsel of pyn voortduur of vererger.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Wit tot naaswit, koeëlvormige setpille met 'n kenmerkende balsamiese reuk.

AANBIEDING:

'n Verpakking met twee PVC stolpverpakings van 6 setpille elk (12 setpille).

BERGINGSINSTRUKSIES:

Bewaar op 'n koel (teen of benede 25 °C), droë plek.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

E/11.8/0515

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:

MDI Healthcare Bk
Andersonstraat 374
Menlo Park, 0081
Suid-Afrika

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

19 June 2018

Registration details:

Botswana B9321890

Namibia 04/11.8/1522

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