

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

Anusol Ointment

COMPOSITION:

Each 1 g of ointment contains:

Bismuth Subgallate	22,50 mg
Bismuth Oxide	8,75 mg
Zinc Oxide	107,50 mg

PHARMACOLOGICAL CLASSIFICATION:

A 11.8 Suppositories and anal ointments.

PHARMACOLOGICAL ACTION:

Anusol Ointment exerts a soothing, emollient action, which helps to relieve inflammation and alleviates pain.

INDICATIONS:

The ointment soothes the pain and irritation of external haemorrhoids (piles) and other related conditions around the anus.

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:

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

Adults:

Apply the ointment as often as necessary.

1. To apply internally, screw off the cap and attach the cleansed applicator nozzle (enclosed).
2. Insert the applicator into the anus and release the desired quantity of ointment.
3. Then apply a thin film of ointment over the external area. The product is nonstaining, however if excess product is applied remove gently with gauze or soft tissue.

SKEDULERINGSSTATUS: S0

EIENDOMSNAAM (EN DOSEERVORM):

Anusol Salf

SAMESTELLING:

Elke 1 g salf bevat:

Bismutsubgallaat	22,50 mg
Bismutoksied	8,75 mg
Sinkoksied	107,50 mg

FARMAKOLOGIESE KLASSIFIKASIE:

A 11.8 Setpille en anale salwe.

FARMAKOLOGIESE WERKING:

Anusol Salf het 'n strelende, versagterende werking, wat help om ontsteking en pyn te verlig.

INDIKASIES:

Die salf streef die pyn en irritasie van uitwendige hemorroïede (aambeie) en ander verwante toestande rondom die anus.

KONTRA-INDIKASIES:

Ernstige rektale patologie. Hemorroïede 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:

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:

Wend die salf so dikwels aan as wat nodig mag wees.

1. Om inwendig aan te wend, skroef die dop af en skroef die gereinigde aanwenderspuit (ingesluit) aan.
2. Steek die aanwender in die anus op en stel die verlangde hoeveelheid salf vry.
3. Wend dan 'n dun lagie salf aan die uitwendige gebied. Die produk vlek nie, maar indien daar te veel daarvan aangewend is, meet dit liggies met gaas of sagte sneespapier verwyder word.

4. After each application the applicator nozzle must be removed and carefully washed in hot water with detergent and then thoroughly rinsed in clear water.

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:

A smooth, buff-coloured ointment with a characteristic balsamic odour.

PRESENTATION:

Tube containing 25 g with an applicator.

STORAGE INSTRUCTIONS:

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

REGISTRATION NUMBER:

E/11.8/0513

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

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

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

19 June 2018

Registration details:

Botswana B9321885
Namibia 04/11.8/1521
Ghana FDB/SD.08-5195
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Nigeria NAFDAC Reg No 04-2918
Tanzania TAN 00,923 D02A WAR
Uganda 1979/13/97
Zambia 082/032 P
Zimbabwe 77/16.3/825

4. Die aanwenderspuit moet na elke aanwending verwyder en versigtig met 'n reinigingsmiddel in warm water gewas word en dan met skoon water afgespoel word.

Kinders: Nie aanbeveel nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

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 simptome en ondersteunend.

IDENTIFIKASIE:

'n Gladde, liggeel-kleurige salf met 'n kenmerkende balsamiese reuk.

AANBIEDING:

Buisie met 25 g met 'n aanwender.

BERIGINGSINSTRUKSIES:

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

REGISTRASIENOMMER:

E/11.8/0513

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

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