

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **Anusol** ointment(bismuth subgallate 22,50 mg, bismuth oxide 8,75 mg, zinc oxide 107,50 mg per 1,0 g ointment).
(Bismuth subgallate, bismuth oxide, zinc oxide).**Read all of this leaflet carefully because it contains important information for you.**

ANUSOL OINTMENT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ANUSOL OINTMENT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ANUSOL OINTMENT with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

- What ANUSOL OINTMENT is and what it is used for
- What you need to know before you use ANUSOL OINTMENT
- How to use ANUSOL OINTMENT
- Possible side effects
- How to store ANUSOL OINTMENT
- Contents of the pack and other information

- What ANUSOL OINTMENT is and what it is used for**
 - ANUSOL OINTMENT belongs to a group of medicines in the form of suppositories and anal ointments.
 - ANUSOL OINTMENT is used to soothe the pain and irritation of external piles and other related conditions around the anus.
- What you need to know before you use ANUSOL OINTMENT**
 - Do not use ANUSOL OINTMENT**
 - If you are allergic to any of the ingredients
 - If you have serious conditions of the rectum
 - In cases of bleeding from the rectum, or if the condition carries on, consult your doctor.

Warnings and precautions

Take special care with ANUSOL OINTMENT: Harmful effects to the nervous system may occur with prolonged or excessive use.

Children

It is not recommended to use ANUSOL OINTMENT in infants and children.

Other medicines and ANUSOL OINTMENT

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

**Pregnancy and breast-feeding:**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

ANUSOL OINTMENT is not likely to affect your ability to drive or use any tools or machines.

3. How to use ANUSOL OINTMENT

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 cottonwool before the medicine is used. The usual dose is as given below.

1 Adults:

- Apply the ointment as often as necessary.
- To apply internally, screw off the cap and attach the cleansed applicator nozzle (enclosed).
- Put the applicator into the anus and release the desired quantity of ointment.
- Then apply a thin film of ointment over the external area. This ointment does not stain, however, if too much ointment is applied remove gently with gauze or soft tissue.
- After each application, the applicator nozzle must be removed and carefully washed in hot water with detergent and then thoroughly rinsed in clear water.

If you have the impression that the effect of ANUSOL OINTMENT is too strong or too weak, talk to your doctor or pharmacist.

Children: Should not be used in children.**2 If you use more ANUSOL Ointment than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take along any medicine that is left and the carton so that the hospital can easily tell what medicine you have used.

3 If you forget to use Anusol Ointment:

Do not use more than the recommended amount of ointment per application.

4. Possible side effects

ANUSOL OINTMENT can have side effects. Allergic reactions may occur. Stop using this ointment immediately if redness, irritation, swelling or pain continues or increases. Not all side effects reported for ANUSOL OINTMENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ANUSOL OINTMENT, please consult your health care provider for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's

publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ANUSOL OINTMENT.**5. How to store ANUSOL OINTMENT**

- Store all medicines out reach of children.
- Store at or below 30 °C, in a dry place.
- Do not use after the expiry date stated on the label or carton. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What ANUSOL OINTMENT contains**

- The active substances are, and each gram contains bismuth subgallate 22,50 mg, bismuth oxide 8,75 mg and zinc oxide 107,50 mg
- The other ingredients are balsam peru, castor oil, cocoa butter, kaolin light, lanolin anhydrous, magnesium stearate and petroleum jelly white.

What ANUSOL OINTMENT looks like and contents of the pack

A beige-coloured ointment with a typical friar's balsam odour. Tube containing 25 g ointment with an applicator.

Holder of Certificate of RegistrationMDI Healthcare CC, 374 Anderson Street, Menlo Park, 0081, South Africa
Customer service: wecare@acdoco.co.za**This leaflet was last revised in**

Date of last revision as approved by SAHPRA: 1 September 1997

Registration number

E/11.8/0513

Access to the corresponding Professional InformationAn online copy of the PI is available at <http://acdoco.co.za/anusol/>**Name and address of manufacturer**

Delpharm Orléans, 5 Avenue de Concy, 45071 Orléans Cedex 2, France

Registration details:Botswana: S3; B9321885
Namibia: NS1; 04/11.8/1521
Ghana: OTC; FDB/SD.08-5195
Kenya: POM; 0429
Malawi: OTC; PMPB/PL 353/1
Nigeria: OTC; 04-2918
Tanzania: POM; TAN 00.923 Do2A WAR
Uganda: POD; 1979/13/97
Zambia: P; 082/032
Zimbabwe: P; 77/16.3/825

LN515803-21 ANUO-4-101120PIL

PASIËNT INLIGTINGSBLAD

SKEDULERING STATUS: **Anusol** salf(bismutsubgallaat 22,50 mg, bismutoksied 8,75 mg, sinkoksied 107,50 mg per 1,0 g salf).
(Bismutsubgallaat, bismutoksied, sinkoksied).**Lees die hele inligtingsblad noukeurig aangesien dit belangrike inligting vir u bevat.**

ANUSOL SALF is beskikbaar sonder 'n dokter se voorskrif vir u om 'n matige siekte te behandel. Nietemin moet u ANUSOL SALF versigtig gebruik om die beste resultate te kry.

- Hou hierdie inligtingsblad. U mag dit dalk weer moet lees.
- Moenie ANUSOL SALF met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker as u meer inligting of advies nodig het.
- U moet u dokter sien as u simptome vererger of nie verbeter na 'n paar dae nie.

Wat is in hierdie inligtingsblad

- Wat ANUSOL SALF is en waarvoor dit gebruik word
- Wat u nodig het om te weet voor u ANUSOL SALF gebruik
- Hoe om ANUSOL SALF te gebruik
- Moontlike nuwe-effekte
- Hoe om ANUSOL SALF te stoor
- Inhoud van die pak en ander inligting

1. Wat ANUSOL SALF is en waarvoor dit gebruik word

- ANUSOL SALF behoort aan 'n groep medisyne in die vorm van setpille en anale salwe.
- ANUSOL SALF streef die pyn en irritasie van uitwendige aambeie en ander verwante kondisies rondom die anus.

2. Wat u nodig het om te weet voor u ANUSOL SALF gebruik

- Moet nie ANUSOL SALF neem**
 - Indien u allergies vir enige van die bestanddele is nie
 - Indien u ernstige kondisies van die rektum het nie
 - Indien u van die rektum bloei nie, of indien die kondisie aanhou, konsulteer u dokter.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met ANUSOL SALF: Skadelike effekte op die senuweestelsel kan voorkom met langdurige of oormatige gebruik.

Kinders

Dit word nie aanbeveel om ANUSOL SALF vir babas en kinders te gebruik nie.

Ander medisyne en ANUSOL SALF:

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

**Swangerskap en borsvoeding:**

Indien u swanger is of borsvoed, dink u mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer om advies voor u hierdie medisyne gebruik.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat ANUSOL SALF jou vermoë om te bestuur of die gebruik van enige gereedskap of masjiene sal beïnvloed.

3. Hoe om ANUSOL SALF te gebruik

Die area om die anale opening behoort met seep en warm water gereinig te word en dan versigtig met sagte sneespapier of watte drooggetik te word (nie vryf nie) voordat medikasie gebruik word. Die gewone dosis word hier onder aangedui.

1 Volwassenes:

- Wend die salf so dikwels aan as wat nodig mag wees.
- Om inwendig aan te wend, skroef die dop af en skroef die gereinigde aanwenderspuit (ingesluit) aan.
- Steek die aanwender in die anus op en stel die verlangde hoeveelheid salf vry.
- Wend dan 'n dun laag salf aan die uitwendige gebied. Die salf vlek nie, maar indien daar te veel daarvan aangewend is, moet dit liggies met gaas of sagte sneespapier verwyder word.
- Die aanwenderspuit moet na elke aanwending verwyder en versigtig met 'n reinigingsmiddel in warm water gewas word en dan met skoon water afgespoel word.

As u onder die indruk is dat die effek van ANUSOL SALF te sterk of te swak is, praat met u dokter of apteker.

Kinders: Behoort nie vir kinders gebruik te word nie.**2 Indien u meer ANUSOL SALF gebruik het as wat u moes:**

In geval van oordosering, raadpleeg u dokter of apteker. Indien een nie beskikbaar is nie, kry hulp by die naaste hospitaal of gifbeheersentrum. Neem enige medisyne wat oor is saam, asook die karton sodat die hospitaal maklik kan vasstel watter medisyne u geneem het.

3 Indien u vergeet om ANUSOL SALF te neem

Moenie meer as die aanbevole hoeveelheid salf per aanwending gebruik nie.

4. Moontlike nuwe-effekte

ANUSOL SALF kan nuwe-effekte hê. Allergiese reaksies kan voorkom. Hou dadelik op om hierdie salf te gebruik indien rooiheid, irritasie, swelling of pyn voortduur of vererger. Nie alle nuwe-effekte wat vir ANUSOL SALF aangemeld is, is in hierdie vouiljet ingesluit nie. Indien u algemene gesondheid agteruitgaan of u enige ongewenste reaksies ervaar terwyl u ANUSOL SALF gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies. Indien u enige nuwe-effekte waarneem wat nie in hierdie vouiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Rapportering van nuwe-effekteAs jy nuwe-effekte kry, praat met jou dokter of apteker. Jy kan ook nuwe-effekte rapporteer aan SAHPRA via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur die rapportering van nuwe-effekte, kan jy help om meer inligting oor die veiligheid van ANUSOL SALF te verskaf.**5. Hoe om ANUSOL SALF te stoor**

- Stoor alle medisyne buite bereik van kinders.
- Bewaar teen of benede 30 °C, in 'n droë plek.
- Moet nie na die vervaldatum wat op die etiket of karton aangedui word gebruik nie. Gee alle ongebruikte medisyne terug aan jou apteker. Moenie van ongebruikte medisyne ontslae raak deur dit in dreineringsstelsels of rioolsisteme (bv. toilette) te gooi nie.

6. Inhoud van die pak en ander inligting**Wat ANUSOL SALF bevat**

- Die aktiewe bestanddele per gram is bismutsubgallaat 22,50 mg, bismutoksied 8,75 mg en sinkoksied 107,50 mg.
- Die ander bestanddele is balsem peru, kasterolie, kakaoboter, kaolin lig, lanolin anhidries, magnesiumstearaat en wit petroleumjellie.

Hoe ANUSOL SALF lyk en inhoud van die pak

'n Liggeel-kleurige salf met 'n kenmerkende balsamiese reuk. Buisie wat 25 g salf bevat met 'n aanwender.

Houer van die RegistrasiesertifikaatMDI Healthcare BK, Andersonstraat 374, Menlopark, 0081, Suid-Afrika
Kliëntediens: wecare@acdoco.co.za**Hierdie inligtingsblad was laas hersien in**

Datum van laaste hersiening soos goedgekeur deur SAHPRA: 1 September 1997

Registrasienumer

E/11.8/0513

Toegang tot die ooreenstemmende professionele inligting'n Aanlyn kopie van die PI is beskikbaar by <http://acdoco.co.za/anusol/>

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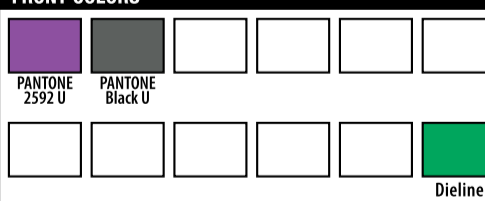


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500 Charles Ewing Boulevard
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800.833.9532**MECHANICAL: ROUND 1****JOB INFORMATION**JOB DESCRIPTION: ANUSOL OINTMENT 25G PIL ZA 2022
BRAND: Anusol
FRONT MATERIAL #: 508109 BACK MATERIAL #:
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