PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ADVANTAN CREAM 0,1 % *w/w*

ADVANTAN FATTY OINTMENT 0,1 % *w/w*

ADVANTAN OINTMENT 0,1 % *w/w*

Methylprednisolone aceponate

Read all of this leaflet carefully before you start using ADVANTAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADVANTAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ADVANTAN is and what it is used for

Advantan is an anti-inflammatory medicine (a corticosteroid) which is intended to be used on the skin.

Advantan reduces the inflammation and allergic reaction of the skin. Therefore, it lessens redness (erythema), fluid build-up (oedema) and fluid oozing from the inflamed skin. It also relieves the itchiness, burning sensation or pain you may feel.

Advantan is used for the treatment of skin conditions which are sensitive to corticosteroids.

2. What you need to know before you use ADVANTAN

Do not use ADVANTAN

- if you are allergic (hypersensitive) to the active substance methylprednisolone aceponate or to any of the other ingredients of Advantan (see also section 6.1)
- If there is Tuberculous or syphilitic processes in the area to be treated; or if there are virus diseases (e.g., herpes simplex, vaccinia, chickenpox, shingles) present.
- if pre-existing eczema or rash has become infected
- on skin areas affected by a skin inflammation that is red/rosy in colour (rosacea), ulcers,
- inflamed diseases of the sebaceous glands (acne vulgaris) or skin folds, groin or under the arm pits (intertrigo acne), or skin diseases accompanied by a thinning of the skin (atrophic skin diseases)
- on skin that is weeping
- on skin areas that show a vaccination reaction i.e., that are red or inflamed after being given a vaccine
- on specific skin inflammation in the area of the upper lip and chin (perioral dermatitis)
- on bacterial, viral or fungal skin infections (unless treated accordingly with a special medicine)
- during pregnancy.

Warnings and precautions

Talk to your doctor before using ADVANTAN

If your doctor diagnoses that your skin disease is accompanied by bacterial or fungal infections, additional specific therapy is required. Talk to your doctor if the infection spreads or gets worse.

Anti-inflammatory medicines (corticosteroids) like the active substance methylprednisolone aceponate in Advantan show strong effects on the body. It is not recommended to use Advantan on large areas of the body or for prolonged periods of time as this will significantly increase the risk of side effects

To reduce the risk of side effects:

- use as little as possible, especially in children
- use only for as long as is absolutely necessary to relieve the skin condition
- you should not get Advantan into your eyes or mouth, open wound or on mucosal surfaces (e.g., the anal and genital area)
- you should not use Advantan on large body surfaces (more than 60 % of your body surface)
- you should not use Advantan under air- and watertight materials including bandages, poorly breathable dressings, clothing or nappies

Contact your doctor if you experience blurred vision or other visual disturbances.

Some of the ingredients of Advantan may cause damage to latex products such as condoms or diaphragms. Therefore, these may no longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist, if you require more information. If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the medicine without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Children

Advantan should not be used in the nappy areas in infants and ideally not be used in infants and young children.

Other medicines and ADVANTAN

Interactions of Advantan with other medicines are not known so far.

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

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 using this medicine.

If your doctor recommends the use of Advantan while breastfeeding, do not apply the medicine on the breasts. Do not bring your baby into contact with the treated areas.

Large-area, prolonged use or use of air- and water-proof dressings should be avoided while breastfeeding.

Fertility

There is no information available on the effect of methylprednisolone aceponate on fertility.

Driving and using machines

Blurry or cloudy vision has been reported as a side effect on patients using Advantan. The frequency of this side effect is unknown. If this happens to you, you should not drive or operate machinery.

Advantan Cream contains butyl hydroxytoluene and cetylstearyl alcohol

Advantan Cream contains butyl hydroxytoluene, which may cause local skin reactions (e.g., contact dermatitis) or irritation to the eyes and mucous membranes, and cetylstearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis).

Advantan cream contains benzyl alcohol

This medicine contains 1.0 g benzyl alcohol in each 100 g. Benzyl alcohol may cause allergic reactions and/or mild local irritation.

3. How to use ADVANTAN

Do not share medicines prescribed for you with any other person.

Always use Advantan exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If not prescribed otherwise by your doctor, the general dosage is as follows:

- apply Advantan thinly once per day to the affected areas of skin;
- always keep the treatment period as short as possible. The duration of use should not exceed 12 weeks in adults and 4 weeks in children.
- if your skin dries out excessively using Advantan Cream, ask your doctor about switching to one of the formulations with a higher fat content (Advantan Ointment or Advantan Fatty Ointment).
- if you have an impression that the effect of Advantan is too strong or too weak, talk to your doctor or pharmacist.

If you use more ADVANTAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use ADVANTAN

Do not use the double amount the next time, but continue the use as prescribed by your doctor or described in the Patient Information leaflet.

If you stop using ADVANTAN

Don’t stop using Advantan without talking to your doctor first.

4. Possible side effects

Advantan can have side effects.

Not all side effects reported for Advantan are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Advantan, please consult your health care provider for advice.

The assessment of the side effects is based on the following frequencies:

Common: less than 1 in 10, but equal to or more than 1 in 100 patients

Uncommon: less than 1 in 100, but equal to or more than 1 in 1 000 patients

Rare: less than 1 in 1000, but equal to or more than1 in 10 000

Very rare: less than 1 in 10 000

Frequency not known: the frequency cannot be estimated from the available information

Advantan Cream

Common:

- a burning sensation and itch at the site of application

Uncommon:

- dryness, redness (erythema), blisters, hair follicle inflammation (folliculitis), rash or tingling at the site of application
- allergic skin reaction (contact dermatitis)

Rare:

- skin infection, swelling or irritation at the site of application
- fungal skin infection
- skin infection producing pus, skin cracks, swelling of the small blood vessels in the skin, thinning of the skin (atrophy), acne

Frequency not known:

- increased hair growth
- stretch marks, specific skin inflammation in the area of the upper lip and chin (perioral dermatitis), skin discolouration, allergic skin reaction (contact dermatitis)
- blurred vision
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Advantan Fatty ointment

Common:

- a burning sensation and hair follicle inflammation (folliculitis) at the site of application

Uncommon:

- pimples with pus, blisters, itch, pain, redness (erythema), or pimples without pus at the site of application,
- skin cracks, swelling of the small blood vessels in the skin

Frequency not known:

- increased hair growth,

- acne, thinning of the skin (atrophy), stretch marks, specific skin inflammation in the area of the upper lip and chin (perioral dermatitis), skin discolouration, allergic skin reaction
- blurred vision
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Advantan Ointment:

Common:

- a burning sensation and itch at the site of application

Uncommon:

- redness (erythema), dryness, blisters, irritation or eczema at the site of application, swelling, lesion, pain
- drug allergy
- *Frequency not known*:
- increased hair growth, thinning of the skin (atrophy), stretch marks, specific skin inflammation in the area of the upper lip and chin (perioral dermatitis), skin discolouration, allergic skin reaction (contact dermatitis)
- blurred vision
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

The use of anti-inflammatory medicines, so-called corticosteroids (like the active substance in Advantan) on the skin can result in the following untoward effects:

- thinning of the skin (atrophy)

- stretch marks
- hair follicle inflammation (folliculitis) at the site of application
- increased body hair growth
- swelling of the small blood vessels in the skin
- specific skin inflammation in the area of the upper lip and chin (perioral dermatitis)
- changes in skin colour
- allergic skin reaction (contact dermatitis).

In rare cases side effects can occur not only at the treatment site but also in completely different areas of the body. This happens if the active substance (a corticosteroid) is absorbed into the body through the skin. This can, for example, increase the pressure in the eye (glaucoma).

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. This includes any possible side effects not listed in this leaflet. 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.
Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via Adcock.AEReports@adcock.com.
By reporting side effects, you can help provide more information on the safety of Advantan.

5. How to store ADVANTAN

Store all medicines out of reach of children.

Store below 30 °C.

Do not use these medicines after the expiry date which is stated on the tube and 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 ADVANTAN contains

The active substance is: methylprednisolone aceponate (MPA).

Each 1g cream, ointment, fatty ointment contains methylprednisolone aceponate 1mg (0,1 %).

The other ingredients are:

Advantan cream

Benzyl alcohol, butylhydroxytoluene, caprylic-capric-myristic-stearic triglyceride (softisan 378), cetostearyl alcohol, decyl oleate, disodium edetate, glycerol 85 per cent,

glycerol monostearate 40-55, hard fat, macrogol stearate 40, type I (polyoxyl-40-stearate), water purified.

Advantan fatty ointment

White soft paraffin, paraffin, liquid, microcrystalline wax, hydrogenated castor oil.

Advantan ointment

Beeswax white, paraffin liquid, dicocoyl pentaerythrityl distearyl citrate + sorbitan sesquioleate + beeswax + aluminum stearates (dehymuls E), paraffin white soft

water purified.

What ADVANTAN looks like and contents of the pack

The fatty ointment is white to yellowish translucent. The ointment is white to

yellowish opaque. The cream is white opaque.

Coated aluminium tubes, each sealed with an aluminium membrane and closed with a plastic screw cap.

Tubes of 15g, 20g, 30g, 50g and 100 g are marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road, Erand Gardens,

Midrand, 1685

South Africa

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

11 September 2023

Registration number (s)

Advantan cream : X/13.4.1/384

Advantan fatty ointment: X/13.4.1/386

Advantan ointment : X/13.4.1/385

Namibia:		
NS2	Advantan cream	04/13.4.1/1433
NS2	Advantan fatty ointment	04/13.4.1/1435
NS2	Advantan ointment	04/13.4.1/1434

PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSTATUS

S4

ADVANTAN CREAM 0,1 % *w/w*

ADVANTAN FATTY OINTMENT 0,1 % *w/w*

ADVANTAN OINTMENT 0,1 % *w/w*

Metielprednisoloonaseponaat

Lees die hele voubiljet noukeurig voor u ADVANTAN begin gebruik

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Vra asseblief u dokter, apteker, verpleegster of ander gesondheidsorgverskaffer as u enige verdere vrae het.
- ADVANTAN is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag hulle skaad al het hulle dieselfde simptome as u.

Wat in hierdie voubiljet is

1. Wat ADVANTAN is en waarvoor dit gebruik word

Advantan is ’n anti-inflammatoriese medisyne (’n kortikosteroïed) wat bedoel is om op die vel gebruik te word.

Advantan verminder die inflammasie en allergiese reaksie van die vel. Dit verminder dus rooiheid (eriteem), opbou van vog (edeem) en lek van vloeistof uit die ontsteekte vel. Dit verlig ook die jeuking, brandsensasie of pyn wat u mag ervaar.

Advantan word gebruik vir die behandeling van veltoestande wat sensitief vir kortikosteroïede is.

2. Wat u moet weet voordat u ADVANTAN gebruik

Moenie ADVANTAN gebruik nie

- as u allergies (hipersensitief) is vir die aktiewe bestanddeel metielprednisoloonaseponaat of enige van ander bestanddele van Advantan (sien ook afdeling 6.1) is.
- as daar Tuberkulose of sifilitiese prosesse in die area wat behandel moet word is; of as daar virussiektes (bv. herpes simpleks, vaccinia, waterpokkies, gordelroos) teenwoordig is.
- as voorafbestaande ekseem of uitslag ontsteek geraak het.
- op vel areas wat met inflammasie besmet is wat rooi/rosig van kleur is (rosacea), sere.
- ontsteekte toestande van die talgkliere (aknee vulgaris) of velvoue, lies en okselholtes (intertrigo aknee), of velsiektes wat met verdunning van die vel gepaard gaan (atrofiese velsiektes).
- op vel wat lek.
- op vel areas wat ’n inentingsreaksie toon, d.i. dis rooi of ontsteek nadat ’n inenting toegedien is.
- op spesifieke inflammasie van die area van die bolip en ken (periorale dermatitis).
- op bakteriese-, virale- of swaminfeksies van die vel (behalwe as dit ooreenkomstig met spesiale medisyne behandel word).
- tydens swangerskap.

Waarskuwings en voorsorgmaatreëls

Praat met u dokter voordat u ADVANTAN gebruik

Bykomende spesifieke behandeling is nodig as u dokter bepaal dat u velsiekte met bakteriese- of swaminfeksies gepaard gaan. Praat met u dokter as die infeksie versprei of erger word.

Anti-inflammatoriese medisyne (kortikosteroïede) soos die aktiewe bestanddeel metielprednisoloonaseponaat in Advantan toon sterk reaksies op die liggaam. Dit word nie aanbeveel om Advantan te gebruik op groot gedeeltes van die liggaam of vir lang tydperke nie, want dit verhoog die risiko van newe-effekte aansienlik.

Om die risiko vir newe-effekte te verminder:

- gebruik so min as moontlik, veral vir kinders.
- gebruik net vir solank as wat absoluut noodsaaklik is om die veltoestand te verlig.
- u moenie dat Advantan in u oë of mond, oop wonde of op mukosale oppervlakke (bv. die anus en geslagsdele) kom nie.
- u moenie Advantan op groot liggaamsoppervlakke (meer as 60% van u liggaamsoppervlak) gebruik nie.
- u moenie Advantan onder lug- en waterdigte materiale gebruik nie, wat verbande en pleisters wat nie kan 'asemhaal' nie, klerasie of doeke insluit.

Kontak u dokter as u versteurde visie ervaar.

Sommige van die bestanddele van Advantan kan lateks-produkte soos kondome of diafragmas beskadig. Hulle kan dus oneffektief as voorbehoeding of as beskerming teen seksueel-oordraagbare siektes soos MIV-besmetting wees. Praat met u dokter of apteker as u meer inligting nodig met. As u toestand tydens gebruik vererger, raadpleeg die persoon wat dit voorgeskryf het – u mag 'n allergiese reaksie ervaar, 'n infeksie hê of u toestand benodig 'n alternatiewe behandeling.

As u toestand herhaaldelik terugkeer kort na staking van behandeling (binne 2 weke) moenie die medisyne weer gebruik sonder om die persoon wat dit voorgeskryf het te raadpleeg nie, tensy daardie persoon u voorheen aanbeveel het om dit te doen. Soek mediese advies voor u die behandeling hervat as u toestand weer opvlam nadat dit opgelos is en die rooiheid strek verder as die oorspronklike area wat behandel is en u ervaar 'n brandgevoel.

Kinders

Advantan moenie op die doek-areas van babas gebruik word nie en ideaal glad nie vir babas en jong kinders gebruik word nie.

Ander medisyne en ADVANTAN

Interaksies van Advantan met ander medisynes is sover onbekend.

Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik.

(Dit sluit alle aanvullende of tradisionele medisynes in.).

Swangerskap, borsvoeding en vrugbaarheid

Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir raad as u swanger is of borsvoed, dink u mag dalk swanger wees of beplan om 'n baba te hê voordat u hierdie medisyne gebruik.

Moenie die medisyne oor u borste aanwend as u dokter aanbeveel dat u Advantan gebruik terwyl u borsvoed nie. Moenie u baba in kontak met die behandelde areas bring nie.

Langdurige gebruik oor groot areas of gebruik van lug- of waterbestande verbande moet tydens borsvoeding vermy word.

Vrugbaarheid

Daar is geen inligting beskikbaar oor die uitwerking van metielpredisoloonasepotaat op vrugbaarheid nie.

Bestuur en bedryf van masjinerie

Wasige of versteurde visie is as newe-effek aangemeld deur pasiënte wat Advantan gebruik. Die gereeldheid van hierdie newe-effek is onbekend. As u dit ervaar moet u nie bestuur of masjinerie

bedryf nie.

Advantan Cream bevat butielhidroksitolueen en setielsterielalkohol

Advantan Cream bevat butielhidroksitolueen, wat plaaslike velreaksies (bv. kontak dermatitis) of irritasie van die oë en slymvliese kan veroorsaak, en setielstearielalkohol, wat plaaslike velreaksies (bv. kontak dermatitis) kan veroorsaak.

Advantan cream bevat bensielalkohol

Hierdie medisyne bevat 1.0 g bensielalkohol in elke 100 g. Bensielalkohol kan allergiese reaksies en/of ligte plaaslike irritasie veroorsaak.

3. Hoe om ADVANTAN te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Gebruik Advantan altyd presies soos u dokter of apteker voorgeskryf het. Bevestig met u dokter of apteker as u onseker is.

Tensy anders deur u dokter voorgeskryf, is die algemene dosis soos volg:

- wend ’n dun laag Advantan een keer per dag op die aangetaste area van die vel aan;
- hou die behandelingsperiode altyd so kort as moontlik. Die duur van gebruik moenie 12 weke vir volwassenes en 4 weke vir kinders oorskry nie.
- as u vel uitermatig uitdroog tydens gebruik van Advantan Cream, vra u dokter oor omskakeling na een van die formulerings met ’n hoër vetinhoud (Advantan Ointment of Advantan Fatty Ointment).
- Praat met u dokter of apteker as u die indruk kry dat die uitwerking van Advantan te sterk of te swak is.

As u meer ADVANTAN gebruik as wat u moet

Raadpleeg u dokter of apteker in geval van oordosering. Kontak die naaste hospitaal of gifsentrum as

nie een van hulle beskikbaar is nie.

As u vergeet om ADVANTAN te gebruik

Moenie die volgende keer dubbel soveel gebruik nie, maar gaan voort om Advantan soos deur u dokter of soos in die Pasiëntinligtingsvoubiljet voorgeskryf, te gebruik.

As u gebruik van ADVANTAN staak

Moenie gebruik van Advantan staak sonder om eers met u dokter te praat nie.

4. Moontlike newe-effekte

Advantan kan newe-effekte hê.

Nie alle newe-effekte wat vir Advantan aangemeld is word in hierdie voubiljet ingesluit nie. Kontak asseblief u gesondheidsorgverskaffer as u algemene gesondheid versleg of u enige nadelige gevolge ervaar terwyl u Advantan gebruik.

Die beoordeling van die newe-effekte is op die volgende gereeldhede gebaseer:

Algemeen: minder as 1 in 10, maar gelykstaande aan of meer as 1 in 100 pasiënte

Ongewoon: minder as 1 in 100, maar gelykstaande aan of meer as 1 in 1 000 pasiënte

Skaars: minder as 1 in 1000, maar gelykstaande aan of meer as1 in 10 000

Baie skaars: minder as 1 in 10 000

Gereeldheid onbekend: die gereeldheid kan nie van die beskikbare inligting bepaal word nie

Advantan Cream

Algemeen:

- 'n brandsensasie en jeuking van die area van aanwending

Ongewoon:

- droogheid, rooiheid (eriteem), blase, inflammasie van haarfollikels (follikulitis), uitslag of tinteling van die area van aanwending

- allergiese velreaksie (kontak dermatitis)

Skaars:

- velinfeksie, swelling of irritasie van die area van aanwending
- swaminfeksie van die vel
- velinfeksie wat etter, gekraakte vel, swelling van die klein bloedvate in die vel, verdunning van die vel (atrofie), aknee

Gereeldheid onbekend:

- toename van haargroei
- rekmerke, spesifieke inflammasie van die vel in die area van die bolip en ken (periorale dermatitis), verkleuring van die vel, allergiese velreaksie (kontak dermatitis)
- versteurde visie
- steroïedonttrekkingsreaksie: 'n Onttrekkingsreaksie kan voorkom na staking van behandeling na aanhoudende gebruik vir uitgerekte periodes met sommige of al die volgende kenmerke; rooiheid van die vel wat verder as die oorspronklike behandelde area strek, 'n brand- of steek-sensasie, intense jeuk, afskilfering van vel, lekkende oop sere.

Advantan Fatty ointment

Algemeen:

- 'n brandsensasie en inflammasie van die haarfollikels (follikulitis) by die area van aanwending

Ongewoon:

- puisies met etter, blase, jeuk, pyn, rooiheid (eriteem), of puisies sonder etter by die area van aanwending,
- gekraakte vel, swelling van die klein bloedselle in die vel

Gereeldheid onbekend:

- toename in haargroei,
- aknee, verdunning van die vel (atrofie), rekmerke, spesifieke inflammasie van die vel in die area van die bolip en ken (periorale dermatitis), verkleuring van die vel, allergiese velreaksie

- versteurde visie
- steroïedonttrekkingsreaksie: 'n Onttrekkingsreaksie kan voorkom met staking van gebruik na aanhoudende gebruik vir uitgerekte periodes met sommige of al die volgende kenmerke; rooiheid van die vel wat verder as die oorspronklike behandelde area strek, 'n brand- of steek-sensasie, intense jeuk, afskilfering van die vel, lekkende oop sere.

Advantan Ointment:

Algemeen:

- 'n brand-sensasie en jeuk op die area van aanwending

Ongewoon:

- rooiheid (eriteem), droogheid, blase, irritasie of ekseem van die area van aanwending, swelling, letsels, pyn
- allergie vir medisynes

Gereeldheid onbekend:

- toename in haargroei, verdunning van die vel (atrofie), rekmerke, spesifieke inflammasie van die vel in die area van die bolip en ken (periorale dermatitis), verkleuring van vel, allergiese velreaksie (kontak dermatitis)
- versteurde visie
- steroïedonttrekkingsreaksie: 'n Onttrekkingsreaksie kan voorkom met staking van gebruik na aanhoudende gebruik vir uitgerekte periodes met sommige of al die volgende kenmerke; rooiheid van die vel wat verder as die oorspronklike behandelde area strek, 'n brand- of steek-sensasie, intense jeuk, afskilfering van die vel, lekkende oop sere.

Die gebruik van anti-inflammatoriese medisynes, sogenaamde kortikosteroïede (soos die aktiewe bestanddeel in Advantan), op die vel kan die volgende nadelige gevolge tot gevolg hê:

- verdunning van die vel (atrofie)
- rekmerke
- inflammasie van die haarfollikel (follikulitis) by die area van aanwending

- toename in groei van liggaamshare
- swelling van die klein bloedvate in die vel
- spesifieke inflammasie van die vel in die area van die bolip en ken (periorale dermatitis)
- verandering in velkleur
- allergiese velreaksie (kontak dermatitis).

Newe-effekte kan in skaars gevalle nie net by die area van behandeling voorkom nie, maar ook in heeltemal ander areas van die liggaam. Dit gebeur as die aktiewe bestanddeel ('n kortikosteroïed) in die liggaam deur die vel opgeneem word. Dit kan, byvoorbeeld, die druk in die oog verhoog (gloukoom).

Lig asseblief u dokter of apteker in as u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie.

Aanmeld van newe-effekte

Praat met u dokter of apteker as u newe-effekte ervaar. Dit sluit enige moontlike newe-effekte wat nie in hierdie voubiljet gelys word nie in. U kan newe-effekte ook by SAHPRA aanmeld via die 6.04 Adverse Drug Reaction Reporting Form, aanlyn gevind onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Vermoedelike nadelige gevolge kan ook by die Houer van die Registrasiesertifikaat aangemeld word aan Adcock.AEReports@adcock.com.
Deur newe-effekte aan te meld kan u ook help met meer inligting oor die veiligheid van Advantan.

5. Hoe om ADVANTAN te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre teen laer as 30 °C.

Moenie medisyne na die vervaldatum soos op die buis of kartondosie aangedui gebruik nie

Gee alle ongebruikte medisyne aan u apteker terug.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van pak en ander inligting

Wat ADVANTAN bevat

Die aktiewe bestanddeel is: metielprednisoloonaseponaat (MPA).

Elke 1g room, salf of vetterige salf bevat 1mg (0,1 %) metielprednisoloonaseponaat.

Die ander bestanddele is:

Advantan cream

Bensielalkohol, butielhidroksitolueen, kapriel-kaprien-miristiese-stearientrigliseried (softisan 378), setostearielalkohol, dekieloleaat, dinatriumedetaat, gliserol 85 persent, gliserolmonostereaat 40-55, harde vet, makrogolstearaat 40, tipe I (polioksiel-40-stearaat), gesuiwerde water.

Advantan fatty ointment

Wit sagte paraffien, paraffien, vloeistof, mikrokristallyne was, gehidrogeneerde kasterolie

Advantan ointment

Wit byewas, paraffien vloeistof, dikokoielpentaeritritieldistearies sitraat + sorbitaanseskiolaat + byewas + aluminumstearate (dehymuls E), wit sagte paraffien, gesuiwerde water.

Hoe ADVANTAN lyk en inhoud van die pak

Die vetterige salf is wit tot gelerig deurskynend. Die salf is wit tot gelerig ondeursigtig. Die room is ondeursigtig wit.

Bedekte aluminiumbuise, elk met ’n aluminium membraan verseël en met ’n plastiese skroefprop toegemaak.

Buise van 15g, 20g, 30g, 50g en 100 g word bemark.

Houer van Registrasiesertifikaat

Adcock Ingram Beperk

1 New Road, Erand Gardens,

Midrand, 1685

Suid-Afrika

Klantediens: 0860 ADCOCK / 232625

Laaste hersiening van hierdie voubiljet

11 September 2023

Registrasienommer(s)

Advantan cream : X/13.4.1/384

Advantan fatty ointment: X/13.4.1/386

Advantan ointment : X/13.4.1/385

Namibië:		
NS2	Advantan cream	04/13.4.1/1433
NS2	Advantan fatty ointment	04/13.4.1/1435
NS2	Advantan ointment	04/13.4.1/1434

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076637 07/2024