Patient Information Leaflet

SCHEDULING STATUS: **S4**

DOVOBET 50 µg/g + 0,5 mg/g ointment

calcipotriol/betamethasone

Read all of this leaflet carefully before you start using DOVOBET

- 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.
- DOVOBET 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 DOVOBET is and what it is used for
2. What you need to know before you use DOVOBET
3. How to use DOVOBET
4. Possible side effects
5. How to store DOVOBET
6. Contents of the pack and other information

1. What DOVOBET is and what it is used for

DOVOBET is used on the skin to treat plaque psoriasis (psoriasis vulgaris) in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin. DOVOBET ointment contains calcipotriol and betamethasone. Calcipotriol helps to bring the rate of skin cell growth back to normal and betamethasone acts to reduce inflammation.

2. What you need to know before you use DOVOBET

Do not use DOVOBET:

- If you are hypersensitive (allergic) to calcipotriol, betamethasone or any of the other ingredients in DOVOBET (listed in section 6).
- If you have problems with calcium levels in the body (ask your doctor).
- If you have certain types of psoriasis: these are erythrodermic, exfoliative and pustular (ask your doctor).
- If your kidneys or liver do not work properly.
- If you are pregnant.

As DOVOBET contains a strong steroid do NOT use on skin affected by:

- skin infections caused by viruses (e.g. cold sores or chicken pox).
- skin infections caused by a fungus (e.g. athlete's foot or ringworm).
- skin infections caused by bacteria.
- skin infections caused by parasites (e.g. scabies).
- tuberculosis (TB).
- perioral dermatitis (red rash around the mouth).
- thin skin, easily damaged veins, stretch marks.
- ichthyosis (dry skin with fish-like scales).
- acne (pimples).
- rosacea (severe flushing or redness of the skin on the face).
- ulcers or broken skin.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before and during use of DOVOBET if:

- you are using other medicines that contain corticosteroids, as you may get side effects.
- you have used this medicine for a long time and plan to stop (as there is a risk your psoriasis will get worse or 'flare up' when steroids are stopped suddenly).

- you have diabetes mellitus (diabetes), as your blood sugar/glucose level may be affected by the steroid.
- your skin becomes infected, as you may need to stop your treatment.
- you have a certain type of psoriasis called guttate psoriasis.
- you experience blurred vision or other visual disturbances.

Take special care with DOVOBET:

- Avoid use on more than 30 % of your body or using more than 15 grams per day
- Avoid using under bandages or dressings as it increases the absorption of the steroid.
- Avoid use on large areas of damaged skin, on mucous membranes or in skin folds (groin, armpits, under breasts) as it increases the absorption of the steroid
- Avoid use on the face or genitals (sex organs) as they are very sensitive to steroids
- Avoid too much exposure to either natural or artificial light.

Children and adolescents

DOVOBET is not recommended for the use in children below the age of 18 years.

Other medicines and DOVOBET

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

Pregnancy and breastfeeding

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.

Do not use DOVOBET if you are pregnant.

If your doctor has agreed that you can breastfeed, take care and do not apply DOVOBET to the breast area.

Driving and using machines

It is not always possible to predict to what extent DOVOBET may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the

measure to which DOVOBET affects them.

DOVOBET should not have any effect on your ability to drive or use machines.

3. How to use DOVOBET

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

DOVOBET is for external use only. Always use DOVOBET exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Instruction for proper use:

- Use only on the affected area and do not use on skin which does not have psoriasis.
- Remove the cap and check that the seal in the tube is not broken before you first use the ointment.
- To break the seal, use the point in the back of the cap.
- Squeeze the ointment onto a clean finger.
- Rub gently into your skin to cover the affected area of psoriasis until most of the ointment has disappeared into the skin.
- Do not bandage, tightly cover or wrap the treated skin area.
- Wash your hands well after using DOVOBET (unless you are using the ointment to treat your hands). This will avoid accidentally spreading the ointment to other parts of your body (especially the face, scalp, mouth and eyes).
- Do not worry if some ointment accidentally gets on normal skin near your psoriasis, but wipe it off if it spreads too far.
- In order to achieve optimal effect, it is recommended not to take a shower or bath immediately after application of DOVOBET ointment.
- After applying the ointment, avoid contact with textiles which are easily stained by grease (e.g. silk).

Adults

Duration of treatment

- Use the ointment once a day. It may be more convenient to use the ointment in the evening.

- The normal initial treatment period is 4 weeks but your doctor may decide on a different treatment period.
- Your doctor may decide on repeated treatment.
- Do not use more than 15 grams in one day.

If you use other calcipotriol containing medicines, the total amount of calcipotriol medicines must not exceed 15 grams per day and the area treated should not exceed 30 % of the total body surface.

If you have the impression that the effect of DOVOBET is too strong or too weak, tell your doctor or pharmacist.

If you use more DOVOBET than you should

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

Contact your doctor if you have used more than 15 grams in one day.

Excessive use of DOVOBET may cause a problem with calcium in your blood, which usually normalises when discontinuing treatment. Your doctor may need to carry out blood tests to check that using too much ointment has not caused a problem with calcium in your blood. Excessive prolonged use can also cause your adrenal glands to stop working properly (these are found near the kidneys and produce hormones).

Treatment is symptomatic (relating to symptoms) and supportive.

If you forget to use DOVOBET

Do not apply a double quantity to make up for forgotten individual applications.

If you stop using DOVOBET

The use of DOVOBET should be stopped as indicated by your doctor. It may be necessary for you to stop this medicine gradually, especially if you have used it for a long time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

DOVOBET can have side effects.

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

Side effects

Tell your doctor or nurse immediately or as soon as possible if any of the following happens. You may have to stop your treatment.

The following side effects have been reported for DOVOBET:

Less frequent:

- Worsening of your psoriasis. If your psoriasis gets worse, tell your doctor as soon as possible.
- Pustular psoriasis may occur (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop using DOVOBET and tell your doctor as soon as possible.

Some side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in DOVOBET. You should tell your doctor as soon as possible if any of the side effects occur. These side effects are more likely to happen after long-term use, use in skin folds (e.g. groin, armpits or under breasts), use under occlusion or use on large areas of skin.

The side effects include the following:

- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.
- Cataracts (signs are cloudy and foggy vision, difficulty seeing at night and sensitivity to light) or an increase in pressure inside the eye (signs are eye pain, red eye, decreased or cloudy vision)
- Infections (because your immune system which fights infections may be suppressed or weakened)
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop using DOVOBET and tell your doctor as soon as possible.

- Impact on the metabolic control of diabetes mellitus (if you have diabetes you may experience fluctuations in the blood glucose levels).

Side effects known to be caused by calcipotriol

- Allergic reactions with deep swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may occur. If you have an allergic reaction, stop using DOVOBET, **tell your doctor immediately or go to the casualty department at your nearest hospital.**
- Treatment with this ointment may cause the level of calcium in your blood or urine to increase (usually when too much ointment has been used). Signs of increased calcium in blood are excessive secretion of urine, constipation, muscle weakness, confusion and coma. **This can be serious and you should contact your doctor immediately.** However, when the treatment is stopped, the levels return to normal.

Less serious side effects

The following side effects may occur with the use of DOVOBET:

Frequent side effects:

- Itching
- Skin exfoliation
- Rash
- Burning sensation of the skin

Less frequent side effects:

- Skin pain or irritation
- Rash with inflammation of the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels (erythema)
- Inflammation or swelling of the hair root (folliculitis)
- Changes in skin colour in the area you have used the ointment

- Infection of the skin
- Thinning of the skin
- Appearance of red or purple discolouration on the skin (purpura or ecchymosis)
- Bacterial or fungal infection of hair follicle (furuncle)
- Allergic reactions
- Hypokalaemic syndrome
- Hypercalcaemia
- Stretch marks
- Sensitivity of the skin to light resulting in a rash
- Acne (pimples)
- Excessive facial or chest hair growth in women (Hirsutism)
- Numbness in fingers
- High blood pressure
- Loss of proteins
- Gastric ulcer
- Dry skin
- Rebound effect: A worsening of symptoms/psoriasis after ended treatment

Frequency not known (frequency cannot be estimated from the available data)

- Blurred vision

Less serious side effects caused by using betamethasone, especially for a long time, include the following.

You should tell your doctor or nurse as soon as possible if you notice any of them.

- Thinning of the skin
- Appearance of surface blood vessels or stretch marks
- Changes in hair growth
- Red rash around the mouth (perioral dermatitis)
- Skin rash with inflammation or swelling (allergic contact dermatitis)

- Golden coloured gel-filled bumps (colloid milia)
- Lightening of skin colour (depigmentation)
- Inflammation or swelling of the hair root (folliculitis).
- Swelling of the lower limbs (Oedema)

Less serious side effects known to be caused by calcipotriol include the following

- Dry skin
- Sensitivity of the skin to light resulting in a rash
- Eczema
- Itching
- Skin irritation
- Burning and stinging sensation
- Redness of the skin due to widening of the small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis.

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, pharmacist or nurse. 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 DOVOBET.

Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via Adcock.AEReports@adcock.com.

5. How to store DOVOBET

Store all medicines out of reach of children.

Store DOVOBET in the original container, in a cool place (at or below 25 ºC).

Keep the container tightly closed.

Do not use after the expiry date stated on the tube. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Shelf life after opening is 12 months.

6. Contents of the pack and other information

What DOVOBET contains:

The active substances are:

Calcipotriol and betamethasone.

One gram of ointment contains 50 micrograms of calcipotriol (52,2 micrograms as monohydrate) and 0,5 mg of betamethasone (0,643 mg as dipropionate).

The other ingredients are:

- liquid paraffin
- all-rac-α-tocopherol
- polyoxypropylene stearyl ether
- white soft paraffin

What DOVOBET looks like and the contents of the pack:

DOVOBET ointment is an off-white to yellow coloured ointment filled into:

Aluminium tubes with polyethylene screw caps.

Tube size: 15, 30, 60, 100 and 120 g.

Polyethylene-aluminium laminate tubes with polyethylene screw cap.

Tube size: 15, 30, 60, 100 and 120 g.

Holder of Certificate of Registration

Adcock Ingram Limited

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Customer Care: 0860 ADCOCK / 232625

Under licence from:

Leo Pharma A/S

Industriparken 55, 2750 Ballerup, Denmark

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Patient Information Leaflet

SKEDULERINGSTATUS: **S4**

DOVOBET 50 µg/g + 0,5 mg/g salf

kalsipotriol/betametasoon

Lees die hele voubiljet noukeurig voordat u DOVOBET begin gebruik

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

Wat in hierdie voubiljet is:

1. Wat DOVOBET is en waarvoor dit gebruik word
2. Wat u moet weet voordat u DOVOBET gebruik
3. Hoe om DOVOBET te gebruik
4. Moontlike newe-effekte
5. Hoe om DOVOBET te bêre
6. Inhoud van die pak en ander inligting

1. Wat DOVOBET is en waarvoor dit gebruik word

DOVOBET word op die vel gebruik om plaakpsoriase (*psoriasis vulgaris*) by volwassenes te behandel. Psoriase word veroorsaak wanneer u velselle te vinnig geproduseer word. Dit veroorsaak rooiheid, afskilfering en verdikking van u vel.

DOVOBET-salf bevat kalsipotriol en betametasoon. Kalsipotriol help om die spoed waarteen die velselle groei tot normaal te herstel en betametasoon help om inflammasie te verminder.

2. Wat u moet weet voordat u DOVOBET gebruik

Moenie DOVOBET gebruik nie:

- As u hipersensitief (allergies) vir kalsipotriol, betametasoon of enige ander bestanddele van DOVOBET (in afdeling 6 gelys) is.
- As u probleme met kalsiumvlakke in die liggaam het (vra u dokter).
- As u sekere tipes psoriase het: dit is eritrodermies, afskilferend en pustulêr (vra u dokter).
- As u niere of lewer nie reg werk nie.
- As u swanger is.

Aangesien DOVOBET 'n sterk steroïed bevat, MOENIE op vel gebruik wat aangetas is deur:

- velinfeksies wat deur virusse (bv. koorsblare of waterpokkies) veroorsaak word.
- velinfeksies wat deur swamme (bv. voetskimmel of omlope) veroorsaak word.
- velinfeksies wat deur bakterieë veroorsaak word.
- velinfeksies wat deur parasiete (bv. brandsiek) veroorsaak word.
- tuberkulose (TB).
- periorale dermatitis (rooi uitslag om die mond).
- dun vel, are wat maklik beskadig word, rekmerke.
- iktiose (droë vel met visskubagtige afskilfering).
- aknee (puisies).
- *rosacea* (erge blosing of rooiheid van die vel in die gesig).
- swere of gebroke vel.

Waarskuwings en voorsorgmaatreëls

Raadpleeg u dokter, verpleegster of apteker voor en tydens gebruik van DOVOBET as:

- u ander medisyne wat kortikosteroïede bevat gebruik, aangesien u newe-effekte kan kry.

- u hierdie medisyne vir ’n lang tyd gebruik het en beplan om dit te staak (as daar ’n risiko is dat u psoriase sal vererger of ‘opvlam’ wanneer die steroïed skielik gestaak word).
- u diabetes mellitus (suikersiekte) het, as u bloedsuiker/glukosevlak deur die steroïed beïnvloed kan word.
- u vel-infeksie kry, want u mag die behandeling moet staak.
- u ’n sekere soort psoriase naamlik guttate psoriase het.
- u versteurde visie of ander sigversteurings ervaar.

Neem spesiale sorg met DOVOBET:

- Vermy gebruik op meer as 30% van u liggaam of meer as 15 gram per dag.
- Vermy om onder verbande of wondbedekkings te gebruik aangesien dit die opname van die steroïed verhoog.
- Vermy gebruik op groot oppervlakke van beskadigde vel, op slymvliese of in velvoue (lieste, oksels, onder borste) aangesien dit die opname van die steroïed verhoog.
- Vermy gebruik op gesig of geslagsdele (geslagsorgane) aangesien hulle baie sensitief tot steroïede is.
- Vermy te veel blootstelling aan natuurlike- of kunsmatige lig.

Kinders en adolessente

DOVOBET word nie aanbeveel vir kinders onder die ouderdom van 18 jaar nie.

Ander medisyne en DOVOBET

Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit aanvullende en tradisionele medisyne in).

Swangerskap en borsvoeding

As u swanger is of borsvoed, dink u mag dalk swanger wees of beplan om ’n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik.

Moenie DOVOBET gebruik as u swanger is nie.

As u dokter toegestem het dat u kan borsvoed, gebruik DOVOBET omsigtig en moet dit nie in die borsarea

aanwend nie.

Bestuur en bedryf van masjinerie

Dit is nie altyd moontlik om te voorspel tot watter mate DOVOBET by die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie aan die bogenoemde aktiwiteite deelneem tot hulle bewus is van die mate waartoe DOVOBET hulle beïnvloed nie.

DOVOBET behoort nie enige invloed op u vermoë om te bestuur of masjinerie te bedryf te hê nie.

3. Hoe om DOVOBET te gebruik

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

DOVOBET is slegs vir uitwendige gebruik. Gebruik DOVOBET altyd presies soos u dokter voorgeskryf het. Bevestig met u dokter of apteker as u nie seker is nie.

Instruksies vir behoorlike gebruik:

- Gebruik slegs op die aangetaste area en moenie op vel wat nie psoriase het gebruik nie.
- Verwyder die proppie en bevestig dat die seël in die buisie nie gebreek is voordat u die salf vir die eerste keer gebruik nie.
- Om die seël te breek, gebruik die punt aan die agterkant van die proppie.
- Druk die salf uit op 'n skoon vinger.
- Vryf liggies in die vel in om die aangetaste area of psoriase te bedek totdat meeste van die salf in die vel verdwyn het.
- Moenie die behandelde vel verbind of styf toedraai of bedek nie.
- Was u hande goed na aanwending van DOVOBET (behalwe as u die salf gebruik om u hande te behandel). Dit sal verhoed dat u per ongeluk die salf na ander dele van u liggaam versprei (veral die gesig, kopvel, mond en oë).
- Moenie bekommerd wees as van die salf per ongeluk op normale vel naby u psoriase kom nie, maar vee dit af as dit te ver versprei.
- Dit word aanbeveel dat u nie onmiddellik na aanwending van DOVOBET-salf stort of bad nie, sodat optimale uitwerking bereik kan word.

- Vermy kontak na aanwending met materiaal wat maklik deur vetterigheid gevlek kan word (bv. sy).

Volwassenes

Duur van behandeling

- Gebruik die salf een keer daagliks. Dit kan meer gerieflik wees om die salf in die aand aan te wend.
- Die normale aanvangsbehandeling-periode is 4 weke maar u dokter mag op 'n ander behandelingstydperk besluit.
- U dokter mag besluit om die behandeling te herhaal.
- Moenie meer as 15 gram per dag gebruik nie.

As u ander kalsipotriol-bevattende medisyne gebruik, moet die totale hoeveelheid kalsipotriol medisyne nie 15 gram per dag oorskry nie en die area wat behandel word moet nie 30% van die totale liggaamsoppervlak oorskry nie.

Stel u dokter of apteker in kennis as u die indruk kry dat die uitwerking van DOVOBET te sterk of te swak is.

Indien u meer DOVOBET aanwend as wat u moet

In die geval van oordosering, raadpleeg u dokter of apteker. Kontak die naaste hospitaal of gifsentrem as nie een van hulle beskikbaar is nie.

Kontak u dokter as u meer as 15 gram in een dag gebruik het.

Oormatige gebruik van DOVOBET kan probleme met kalsium in u bloed veroorsaak, wat gewoonlik normaliseer by staking van die behandeling. U dokter mag bloedtoetse moet doen om te bevestig dat die gebruik van te veel salf nie probleme met die kalsium in u bloed veroorsaak het nie. Oormatig verlengde gebruik kan ook veroorsaak dat u byniere ophou om behoorlik te werk (byniere word naby die niere gevind en vervaardig hormone).

Behandeling is simptomaties (verwant aan simptome) en ondersteunend.

Indien u vergeet om DOVOBET te gebruik

Moenie ’n dubbel hoeveelheid aanwend om op te maak vir vergete individuele aanwendings nie.

Indien u ophou om DOVOBET te gebruik

Die gebruik van DOVOBET moet gestaak word soos deur u dokter voorgeskryf. Dit mag nodig wees om hierdie medisyne geleidelik te staak, veral as u dit vir ’n lang tydperk gebruik het.

Vra u dokter of apteker as u enige verdere vrae oor die gebruik van die medisyne het.

4. Moontlike newe-effekte

DOVOBET kan newe-effekte hê.

Nie alle newe-effekte vir DOVOBET aangemeld word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u gesondheidsorgverskaffer vir advies as u algemene gesondheid verswak of u ongewenste effekte tydens gebruik van DOVOBET ervaar.

Newe-effekte

Vertel u dokter of verpleegster onmiddellik of so gou as moontlik as enige van die volgende gebeur. U mag die behandeling moet staak.

Die volgende newe-effekte is vir DOVOBET aangemeld:

Minder gereeld:

- Verergering van u psoriase. Lig u dokter so gou as moontlik in as u psoriase vererger.
- Pustulêre psoriase mag voorkom (’n rooi area met gelerige pustels, gewoonlik op die hande of voete). As u dit opmerk, staak gebruik van DOVOBET onmiddellik en lig u dokter so gou as moonlik in.

Sommige newe-effekte word veroorsaak deur betametasoon (’n sterk steroïed), een van die bestanddele in DOVOBET. U moet u dokter so gou as moontlik inlig indien enige newe-effekte voorkom. Hierdie newe-effekte is meer geneig om te gebeur na langtermyn gebruik, gebruik in velvoue (bv. lieste, oksels en onder die borste), onder okklusie of gebruik op groot oppervlakke van die vel.

Die newe-effekte sluit die volgende in:

- U byniere kan ophou om behoorlik te werk. Tekens hiervan is moegheid, depressie en angstigheid.
- Katarakte (tekens hierevan is versteurde visie, moeilike nagsig en sensitiwiteit tot lig) of ’n toename in druk binne-in die oog (tekens is oogpyn, rooi oê, verminderde of versteurde visie)
- Infeksies (omdat u immuunstelsel wat infeksies beveg onderdruk of verswak is)
- Pustulêre psoriase (’n rooi area met gelerige pustels, gewoonlik op die hande en voete). As u hierdie opmerk, staak gebruik van DOVOBET en lig u dokter so gou as moontlik in.
- Impak op die metaboliese beheer van diabetes mellitus (as u suikersiekte het kan u bloedglukosevlak-wisselings ervaar).

Newe-effekte wat deur kalsipotriol veroorsaak word

- Allergiese reaksies met diep swelling van die gesig of ander liggaamsdele soos die hande en voete. Swelling van die mond/keel en probleme om asem te haal mag voorkom. Staak gebruik van DOVOBET as u allergiese reaksies het, **lig u dokter onmiddellik in of gaan na die ongevalle afdeling by u naaste hospitaal.**
- Behandeling met hierdie salf mag veroorsaak dat die kalsiumvlakke in u bloed of urine verhoog (gewoonlik wanneer te veel salf gebruik is). Tekens van verhoogde kalsium in die bloed is oormatige urienuitskeiding, hardlywigheid, spierswakheid, verwarring en koma. **Hierdie kan ernstig wees en u moet u dokter onmiddellik kontak.** Wanneer die behandeling egter gestaak is, keer die vlakke gewoonlik terug na normaal.

Minder ernstige newe-effekte

Die volgende newe-effekte mag met die gebruik van DOVOBET voorkom:

Gereelde newe-effekte:

- Jeuking
- Velafskilfering
- Uitslag
- Brandgevoel van vel

Minder gereelde newe-effekte:

- Pyn of irritasie van die vel
- Uitslag met inflammasie van die vel (dermatitis)
- Rooiheid van die vel as gevolg van die verwyding van die klein aartjies (eriteem)
- Inflammasie of swelling van die haarfollikel (follikulitis)
- Verandering van die velkleur in die area waar die salf aangewend is
- Infeksie van die vel
- Verdunning van die vel
- Voorkoms van rooi of pers verkleuring van die vel (purpura of ekchimose)
- Bakteriese of swaminfeksie van die haarfollikel (furunkel)
- Allergiese reaksies
- Hipokalemiese sindroom
- Hiperkalsemie
- Rekmerke
- Sensitiwiteit van die vel tot lig, wat uitslag veroorsaak
- Aknee (puisies)
- Oortollige gesig- of borshaar-groei by vroue (Hirsutisme)
- Gevoelloosheid van vingers
- Hoë bloeddruk
- Verlies van proteïene
- Maagsweer
- Droë vel
- Terugslageffek: ’n Verergering van simptome/psoriasena na staking van behandeling

Gereeldheid onbekend (gereeldheid kan nie met beskikbare inligting geraam word nie)

- Versteurde visie

Minder ernstige newe-effekte wat deur betametasoon gebruik veroorsaak word, veral met langdurige gebruik, sluit die volgende in. U moet u dokter of verpleegster so gou as moontlik inlig as u enige van hulle opmerk.

- Verdunning van die vel
- Voorkoms van oppervlak-bloedvate of rekmerke
- Verandering in haargroei
- Rooi uitslag om die mond (periorale dermatitis)
- Veluitslag met uitslag of swelling (allergiese kontak dermatitis)
- Goudkleurige jelliegevulde knoppies (kolloïede milia)
- Verligting van velkleur (depigmentasie)
- Inflammasie of swelling van die haarwortel (follikulitis).
- Swelling van die onderste ledemate (Edeem)

Minder ernstige newe-effekte wat deur kalsipotriol veroorsaak word sluit die volgende in

- Droë vel
- Sensitiwiteit van die vel tot lig, wat uitslag tot gevolg het
- Ekseem
- Jeuking
- Velirritasie
- Brand- en steekgevoel
- Rooiheid van die vel as gevolg van die verwyding van die klein aartjies (eriteem)
- Uitslag
- Uitslag met inflammasie van die vel (dermatitis)
- Verergering van psoriase.

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

Aanmelding van newe-effekte

As u newe-effekte ervaar, praat met u dokter of apteker of verpleegster. U kan ook newe-effekte aanmeld by SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form**", aanlyn beskikbaar onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan u help om meer inligting te voorsien oor die veiligheid van DOVOBET.

Daarbenewens kan vermeende ongewenste reaksies ook by die Houer van die Registrasiesertifikaat aangemeld word via Adcock.AEReports@adcock.com.

5. Hoe om DOVOBET te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre DOVOBET in die oorspronklike houer, in 'n koel plek (teen of laer as 25 ºC).

Hou die houer dig toe.

Moenie na die vervaldatum wat op die buis verskyn gebruik nie. Gee alle ongebruikte medisyne aan u apteker terug.

Moenie met medisyne wegdoen in dreine of rioolstelsels (bv. toilette) nie.

Raklewe na dit oopgemaak is, is 12 maande.

6. Inhoud van pak en ander inligting

Wat DOVOBET bevat:

Die aktiewe bestanddele is:

Kalsipotriol en betametasoon.

Een gram salf bevat 50 mikrogram kalsipotriol (52,2 mikrogram as monohidraat) en 0,5 mg betametasoon (0,643 mg as dipropionaat).

Die ander bestanddele is:

- vloeibare paraffien

- all-rac-α-tokoferol
- poloksipropileenstearieleter
- wit sagte paraffien

Hoe DOVOBET lyk en inhoud van die pak:

DOVOBET-salf is ’n naaswit tot geelkleurige salf in:

Aluminiumbuise met poli-etileen skroefproppe.

Buisgrootte: 15, 30, 60, 100 en 120 g.

Poli-etileen-aluminium gelamineerde buise met poli-etileen skroefprop.

Buisgrootte: 15, 30, 60, 100 en 120 g.

Houer van Registrasiesertifikaat

Adcock Ingram Beperk

1 New Road

Erand Gardens,

Midrand, 1685

Klantediens: 0860 ADCOCK / 232625

Onder lisensie van:

Leo Pharma A/S

Industriparken 55, 2750 Ballerup, Denmark

Laaste hersiening van hierdie voubiljet

28 Julie 2023

Registrasienommer

37/13.9.1/0241

Namibië: NS2 10/13.9.1/0489

adcock ingram

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