

SILVOBLAZE OTC

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

[S2]

SILVOBLAZE OTC 10 mg/1 g of cream
Silver sulfadiazine

Read all of this leaflet carefully because it contains important information for you

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

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

What is in this leaflet

1. What SILVOBLAZE OTC is and what it is used for
2. What you need to know before you use SILVOBLAZE OTC
3. How to use SILVOBLAZE OTC
4. Possible side effects
5. How to store SILVOBLAZE OTC
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1. What SILVOBLAZE OTC is and what it is used for

SILVOBLAZE OTC is used as a topical wound dressing for the short term treatment of minor burns.

2. What you need to know before you use SILVOBLAZE OTC

Do not use SILVOBLAZE OTC:

- If you are hypersensitive (allergic) to silver sulfadiazine, sulphonamides (antibiotics used to treat bacterial infection and some fungal infections), or any other ingredients of SILVOBLAZE OTC (listed in section 6).
- If you are allergic to peanuts or soya. SILVOBLAZE OTC contains arachis oil (peanut oil).
- If you have liver or kidney problems.
- If you have a rare metabolic disorder which leads to difficulty making a chemical called haem – a constituent of many important proteins in the body (porphyria).
- If you are pregnant or breastfeeding your baby.
- If the patient is a premature infant or infant during the first months of life.

Warnings and precautions

Take special care with SILVOBLAZE OTC:

- SILVOBLAZE OTC is for external use only.
- If you are sensitive (allergic) to sulphonamides (antibiotics used to treat bacterial infections and some fungal infections), furosemide, thiazide diuretics (sometimes called “water tablets”), sulphonylureas (a group of medicines used to treat type 2 diabetes) or carbonic anhydrase inhibitors (medicine used in the management and treatment of high pressure in the eye, a build-up of pressure around the brain, altitude sickness, congestive heart failure and epilepsy/seizures) as you may be sensitive to SILVOBLAZE OTC.
- Some patients using SILVOBLAZE OTC (which contains silver sulfadiazine) may have skin reactions. SILVOBLAZE OTC may increase the time for dead tissue (eschar) to separate from the body. It may also change the appearance of burn wound and the chance that a fungal infection could develop in the wound is possible.
- If you have a deficiency of the enzyme known as glucose-6-phosphate dehydrogenase which may cause paleness, extreme tiredness or dizziness, fast heartbeat, fast breathing or shortness of breath, yellowing of the eyes and skin and an enlarged spleen.
- When a fall in white blood cell count is demonstrated (high fever, chills and sweating), your blood count should be monitored to ensure that it returns to normal within a few days.
- When SILVOBLAZE OTC is applied to a large area and when the lesion(s) is/are deep as appreciable amounts of SILVOBLAZE OTC may be absorbed and cause systemic side effects such as blue-grey discolouration of the skin and damage to nerve cells, nerve fibres and nerve coverings.
- As there is a risk of crystallisation in the urine. It may be reduced by the intake of adequate fluids and normalisation of the acid base.
- When exposed to sunlight as local skin sensitivity to SILVOBLAZE OTC may occur.
- When a rash appears, treatment should be discontinued because of the danger of a severe allergic reaction called Stevens-Johnson syndrome (characterised by severe blisters and bleeding in the lips, eyes, mouth, nose and genitals).
- When you are an elderly patient as you may be particularly prone to adverse reactions.
- If you have acquired immunodeficiency syndrome (AIDS) as you may be particularly prone to adverse reactions.
- If you have severe burns covering a large area, your body may absorb more of the sulfadiazine in SILVOBLAZE OTC. Because of this, doctors will monitor your blood and kidney function to make sure it's safe. They may also check your urine for crystals.
- Additionally, an ingredient in SILVOBLAZE OTC (propylene glycol) can affect some laboratory test results, so your doctors will keep that in mind when reviewing your tests.

Other medicines and SILVOBLAZE OTC:

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

SILVOBLAZE OTC may enhance the effects of the following medicines:

- Oral antidiabetic medicines.
- Blood thinning tablets (warfarin).
- Methotrexate used in the treatment of cancer and autoimmune diseases (conditions in which the body's immune system attacks its own healthy cells).
- Antiepileptic medicine called phenytoin.

SILVOBLAZE OTC can increase the antidiabetic effect of sulphonylurea medicines used in the treatment of diabetes.

Concurrent use of cimetidine (medicine used to lower stomach acid) and SILVOBLAZE OTC, may contribute to a decrease in white blood cells and the development of side effects.

SILVOBLAZE OTC may affect the working of enzymatic debriding agents (certain medicine enzymes, prescribed to remove necrotic or dead tissue).

Pregnancy and breastfeeding

SILVOBLAZE OTC should not be used during pregnancy or while you are 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 using SILVOBLAZE OTC.

Driving and using machines

SILVOBLAZE OTC should have no or limited effect on your ability to drive a vehicle or operate machinery but the effect on you as individual should be known before you drive a vehicle or operate machines.

SILVOBLAZE OTC contains cetyl alcohol and propylene glycol

SILVOBLAZE OTC contains cetyl alcohol which may cause local skin reactions (e.g. skin rash) and 100 mg/g propylene glycol which may cause skin irritation.

SILVOBLAZE OTC contains arachis oil and methyl/propyl hydroxybenzoates

SILVOBLAZE OTC contains arachis oil (peanut oil). If you are allergic to peanut or soya, do not use SILVOBLAZE OTC.

SILVOBLAZE OTC may cause allergic reactions (possibly delayed).

3. How to use SILVOBLAZE OTC

Do not share medicines prescribed for you with any other person. Always use SILVOBLAZE OTC exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Do not swallow SILVOBLAZE OTC cream. SILVOBLAZE OTC should be applied daily in a layer approximately 3 – 5 mm thick with a sterile gloved hand or spatula. The wound may be dressed or left open. One container of SILVOBLAZE OTC should be reserved for one patient and any remaining cream should be discarded on completion of treatment. There are some bacteria which may develop resistance to silver sulfadiazine and you are advised to consult with your doctor, if you have been using SILVOBLAZE OTC without any noticeable result in the healing of your minor burn.

If you use more SILVOBLAZE OTC than you should

If an allergic reaction occurs discontinue use, treatment is symptomatic and supportive. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SILVOBLAZE OTC

If you miss an application of SILVOBLAZE OTC cream, apply the dose as soon as you remember, and continue with the normal dosing schedule.

4. Possible side effects

SILVOBLAZE OTC can have side effects.

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

If any of the following happens, stop using SILVOBLAZE OTC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SILVOBLAZE OTC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- a drop in blood sugar levels,
- kidney disorders (lower back pain, passage of blood in the urine, production of an abnormally small amount of urine, failure of the kidneys to pass urine),
- crystallisation in urine (therefore, adequate fluid intake and normalisation of the acid base balance are important),
- leucopenia, which is when you have a low level of white blood cells and is characterised by frequent infections.

Less frequent side effects:

- any symptoms that may indicate a problem with the cells in your blood, the problems being, an acute deficiency of certain blood cells, failure of blood cell production, a decrease in the number of blood platelets, reduction in the number of white blood cells, change in blood clotting time or a blood cell condition called eosinophilia (an increase in some white blood cells). The symptoms may include rash, itching, asthma, fatigue, fever, sores in the mouth or throat, shortness of breath, pale skin, easy bruising, nosebleeds, bleeding gums, prolonged bleeding from cuts,
- kidney failure,
- local pain and irritation, fungal infection of the wound.

Side effects with unknown frequency:

- Stevens-Johnson syndrome, the symptoms may include a painful red or purplish rash that spreads and blisters, and peeling of the skin,
- toxic epidermal necrolysis (severe peeling and necrosis of the skin),
- yellowing of the skin and eyes, also called jaundice,
- life-threatening condition known as “kernicterus” (jaundice of the brain) in babies during the first months of life by interfering with normal metabolism.in newborns, especially premature babies may occur. It can cause movement issues, hearing loss, and developmental delays,
- fits or seizures (convulsions),
- thyroid problems (hypothyroidism),
- inflammation of the lining of the brain characterised by fever, chills, headache, loss of appetite, nausea, vomiting and fatigue (aseptic meningitis (aseptic meningitis),
- benign intracranial hypertension (high pressure in spaces surrounding the brain and spinal cord),
- systemic lupus erythematosus (characterised by fatigue, joint pain, rash and fever),
- inflammation of the pancreas (pancreatitis),
- allergic reaction of your body to certain medications or infections (serum sickness), causing fever, rash, joint pain, and swelling. It usually improves once the treatment stops,
- liver necrosis,
- pulmonary eosinophilia, fibrosing alveolitis diseases causing for instance symptoms similar to asthma,
- narrowing or blockage of blood vessels,
- heart problems (adverse effect because of possible allergic reaction).

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea (feeling sick), vomiting (being sick), loss of appetite (anorexia), diarrhoea
- rash at site of application,
- fever, application site burning,
- skin sensitivity to sunlight,
- painful bumps under skin.

Less frequent side effects:

- purplish grey discoloration of the skin.

Side effects with unknown frequency:

- dizziness,
- headache,
- fatigue,
- drowsiness,
- trouble falling asleep,
- depression,
- weakness, numbness and pain in the hands and feet,
- vision disturbances or loss of vision,
- spinning sensation (vertigo),
- feeling disconnected from reality (psychoses),
- impaired balance or coordination (ataxia).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SILVOBLAZE OTC.

5. How to store SILVOBLAZE OTC

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- 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 SILVOBLAZE OTC contains:

Each gram contains 10 mg silver sulfadiazine. The other ingredients are arachis oil (hydrogenated), cetyl alcohol, polysorbate 60, purified water, propylene glycol, methyl paraben, propyl hydroxybenzoate.

Preservatives: methyl hydroxybenzoate (0,15 % m/m) and propyl hydroxybenzoate (0,05 % m/m).

What SILVOBLAZE OTC looks like and contents of the pack

SILVOBLAZE OTC is an odourless, white homogenous cream.

SILVOBLAZE OTC will be packed in a 50 g aluminium membrane closed tube with pre-printed exterior coating and epoxy phenolic lining. The cap is a conical LDPE (low density polyethylene) screw cap with a piercing pin for the membrane.

Holder of certificate of registration

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Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.

SILVOBLAZE OTC

PASIËNT INLIGTINGSAMFLET

SKEDULERINGSTATUS

[52]

SILVOBLAZE OTC 10 mg/1 g room
Silwer sulfadiasien

Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou

- SILVOBLAZE OTC is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n ligte siekte te behandel. Nietemin moet jy steeds SILVOBLAZE OTC versigtig gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie SILVOBLAZE OTC met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter sien as jou simptome vererger of nie verbeter nie.

Wat hierdie pamflet bevat

1. Wat SILVOBLAZE OTC is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy SILVOBLAZE OTC gebruik
3. Hoe om SILVOBLAZE OTC te gebruik
4. Moontlike nuwe-effekte
5. Hoe om SILVOBLAZE OTC te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat SILVOBLAZE OTC is en waarvoor dit gebruik word

SILVOBLAZE OTC word gebruik as 'n kortermyn topikale behandeling vir geringe brandwonde.

2. Wat jy moet weet voordat jy SILVOBLAZE OTC gebruik

Moenie SILVOBLAZE OTC gebruik:

- As jy hipersensitief (allergies) is vir silwersulfadiasien, sulfonamiede (antibiotika wat gebruik word om bakteriële infeksie en sommige swaminfeksies te behandel), of enige ander bestanddele van SILVOBLAZE OTC (gelys in afdeling 6).
- As jy allergies is vir grondboontjies of soja. SILVOBLAZE OTC bevat arachis-olie (grondboontjie-olie).
- As jy lewer- of nierprobleme het.
- As jy 'n seldsame metabolisme afwyking het wat lei tot probleme met die maak van 'n chemikalie genaamd heem – 'n bestanddeel van baie belangrike proteïene in die liggaam (porfirie).
- As jy swanger is om jou baba te borsvoed.
- As die pasiënt 'n premature baba of baba gedurende die eerste maande van lewe is.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met SILVOBLAZE OTC:

- SILVOBLAZE OTC is slegs vir eksterne gebruik.
- As jy sensitief (allergies) is vir sulfonamiede (antibiotika wat gebruik word om bakteriële infeksies en sommige swaminfeksies te behandel), furosemied, tiasieddiuretika (soms genoem “waterablette”), sulfonilureums (‘n groep medisyne wat gebruik word om tipe 2-diabetes te behandel) of koolsuur-anhidrase-in hibeerders wat gebruik word in die behandeling van 'n hoë-druk-, opbou- en opbou-inhibeerders van die oog, druk rondom die brein, hoogtesiekte, kongestiewe hartversaking en epilepsie/aanvalle), aangesien jy sensitief kan wees vir SILVOBLAZE OTC.
- Sommige pasiënte wat SILVOBLAZE OTC gebruik (wat silwersulfadiasien bevat) kan velreaksies hê. SILVOBLAZE OTC kan die tyd vir dooie weefsel (korst) verleng om van die liggaam te skei. Dit kan ook die voorkoms van brandwond verander en die kans dat 'n swaminfeksie in die wond kan ontwikkel, is moontlik.
- As jy 'n tekort aan die ensiem bekend as glukose-6- fosfaatdehidrogenase het wat bleekheid, uiterste moegheid of duiseligheid, winnige hartklop, winnige asemhaling of kortasem, vergeling van die oë en vel en 'n vergrote milt kan veroorsaak.
- Wanneer 'n daling in witbloedseltelling gedemonstreer word (hoë koors, kouekoors en sweet), moet jou bloedselling gemonitor word om te verseker dat dit binne 'n paar dae na normaal terugkeer.
- Wanneer SILVOBLAZE OTC op 'n groot area toegedien word en wanneer die letsel(s) diep is, kan aansienlike hoeveelhede SILVOBLAZE OTC geabsorbeer word en sistemiese nuwe-effekte veroorsaak soos blougrys verkleuring van die vel en skade aan senu weeselle, senuweevesels en senuweebedekkings.
- Aangesien daar 'n risiko van kristallisasie in die urine is. Dit kan verminder word deur die inname van voldoende vloeistowwe en normalisering van die suurbasis.
- Wanneer dit aan sonlig blootgestel word, kan plaaslike velsensitiwiteit vir SILVOBLAZE OTC voorkom.
- Wanneer 'n uitslag voorkom, moet behandeling gestaak word weens die gevaar van 'n ernstige allergiese reaksie genaamd Stevens-Johnson-sindroom (gekenmerk deur erge blase en bloeding in die lippe, oë, mond, neus en geslagsdele).
- Wanneer jy 'n bejaarde pasiënt is, aangesien jy dalk veral geneig is tot nadelige reaksies.
- As jy immuniteitsgebreksindroom (VIGS) opgedoen het, aangesien jy dalk veral geneig is tot nadelige reaksies.
- As jy ernstige brandwonde het wat 'n groot area bedek, kan jou liggaam meer van die sulfadiasien in SILVOBLAVE OTC absorbeer. As gevolg hiervan sal dokters jou bloed- en nierfunksie monitor om seker te maak dit is veilig. Hulle kan ook jou urine nagaan vir kristalle.
- Boonop kan 'n bestanddeel in SILVOBLAZE OTC (propieleenglikol) sommige laboratoriumtoetsresultate beïnvloed, so jou dokters sal dit in gedagte hou wanneer hulle jou toetse hersien.

Ander medisyne en SILVOBLAZE OTC:

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

SILVOBLAZE OTC kan die uitwerking van die volgende medisyne versterk:

- Orale anti-diabetiese medisyne.
- Bloedverdundingstablette (warfarin).
- Metotreksaat wat gebruik word in die behandeling van kanker en outo-immuun siektes (toestande waarin die liggaam se immuunstelsel sy eie gesonde selle aanval).
- Anti-epileptiese medisyne genoem fenitoien.

SILVOBLAZE OTC kan die anti-diabetiese effek van sulfonilureummedisyne wat in die behandeling van diabetes gebruik word, verhoog. Gelyktydige gebruik van simetiden (medisyne wat gebruik word om maagsuur te verlaag) en SILVOBLAZE OTC kan bydra tot 'n afname in witbloedselle en die ontwikkeling van nuwe-effekte. SILVOBLAZE OTC kan die werking van ensiematiese debrideringsmid-dels (sekere medisyne-ensieme, voorgeskryf om nekrotiese of dooie weefsel te verwyder) beïnvloed.

Swangerskap en borsvoeding

SILVOBLAZE OTC moet nie tydens swangerskap of terwyl jy borsvoed gebruik word nie.

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy SILVOBLAZE OTC gebruik.

Bestuur en gebruik van masjiene

SILVOBLAZE OTC behoort geen of beperkte uitwerking te hê op jou vermoë om 'n voertuig te bestuur of masjinerie te bestuur nie, maar die effek op jou as individu moet bekend wees voordat jy 'n voertuig bestuur of masjiene gebruik.

SILVOBLAZE OTC bevat setielalkohol en propieleenglikol

SILVOBLAZE OTC bevat setielalkohol wat plaaslike velreaksies (bv. veluitslag) kan veroorsaak en 100 mg/g propieleenglikol wat velirritasie kan veroorsaak.

SILVOBLAZE OTC bevat arachis-olie en metiel/propyl-hidroksibensoate

SILVOBLAZE OTC bevat arachis-olie (grondboontjie-olie). As jy allergies is vir grondboontjies of soja, moenie SILVOBLAZE OTC gebruik nie.

SILVOBLAZE OTC kan allergiese reaksies veroorsaak (moontlik vertraag).

3. Hoe om SILVOBLAZE OTC te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Gebruik altyd SILVOBLAZE OTC presies soos beskryf in hierdie pamflet of soos jou dokter of apteker jou vertel het. Jy moet jou dokter of apteker raadpleeg as jy nie seker is nie. Moenie SILVOBLAZE OTC room sluk nie. SILVOBLAZE OTC moet daaglik toegedien word in 'n laag van ongeveer 3 – 5 mm dik met 'n steriele handskoën of spatel. Die wond kan bedek word of oopgelaat word. Een houer SILVOBLAZE OTC moet vir een pasiënt gereserveer word en enige oorblywende room moet weggegooi word na voltooiing van behandeling. Daar is 'n paar bakterieë wat weerstand teen silwersulfadiasien kan ontwikkel en jy word aangeraai om met jou dokter te konsulteer as jy SILVOBLAZE OTC gebruik het sonder enige merkbare resultaat in die genesing van jou geringe brandwond.

As jy meer SILVOBLAZE OTC gebruik as wat jy moet

As 'n allergiese reaksie voorkom, staak die gebruik, behandeling is simptomaties en ondersteunend. In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om SILVOBLAZE OTC te gebruik

As jy 'n toediening van SILVOBLAZE OTC room mis, dien die dosis toe sodra jy onthou, en gaan voort met die normale doseringskedule.

4. Moontlike nuwe-effekte

SILVOBLAZE OTC kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir SILVOBLAZE OTC aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar tydens die gebruik van SILVOBLAZE OTC, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om SILVOBLAZE OTC te gebruik en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- flou word.

Dit is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op SILVOBLAZE OTC gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

Gereelde nuwe-effekte:

- 'n daling in bloedsuikervlakke,
- nierafwykings (laerugpyn, bloedvloeï in die urine, produksie van 'n abnormale klein hoeveelheid urine, versuim van die niere om te urineer),
- kristallisasie in urine (dus is voldoende vloeïstofinname en normalisering van die suurbasisbalans belangrik),
- leukopenie, wat is wanneer jy 'n lae vlak van witbloedselle het en gekenmerk word deur gereelde infeksies.

Minder gereelde nuwe-effekte:

- enige simptome wat 'n probleem met die selle in jou bloed kan aandui, die probleme is, 'n akute tekort aan sekere bloedselle, mislukking van bloedselproduksie, 'n afname in die aantal bloedplaatjies, vermindering in die aantal witbloedselle, verandering in bloedstollingstyd of 'n bloedseltoestand genaamd eosinofilie ('n toename in sommige witbloedselle). Die simptome kan insluit uitslag, jeuk, asma, moegheid, koors, sere in die mond of keel, kortasem, bleek vel, maklike kneusing, neusbloeding, bloeiende tandvleis, langdurige bloeding van snye,
- nierversaking,
- plaaslike pyn en irritasie, swaminfeksie van die wond.

Neuwe-effekte met onbekende frekwensie:

- Stevens-Johnson-sindroom, die simptome kan 'n pynlike rooi of pers uitslag insluit wat versprei en blase, en afskilfering van die vel,
- toksiese epidermale nekrolisie (ernstige afskilfering en nekrose van die vel),
- vergeling van die vel en oë, ook genoem geelsug,
- lewensgevaarlike toestand bekend as “kernicterus” (geelsug van die brein) by babas gedurende die eerste maande van die lewe deur inneming met normale metabolisme by pasgeborenes kan veral premature babas voorkom. Dit kan bewegingsprobleme, gehoorverlies en ontwikkelingsagterstande veroorsaak,
- aanvalle of aanvalle (stuip),
- skildklierprobleme (hipotirose),
- ontsteking van die voering van die brein wat gekenmerk word deur koors, kouekoors, hoofpyn, verlies aan eetlus, naarheid, braking en moegheid (aseptiese meningitis (aseptiese meningitis),
- benigne intrakraniale hipertensie (hoë druk in spasies rondom die brein en rugmurg),
- sistemiese lupus erythematosus (gekenmerk deur moegheid, gewrigspyn, uitslag en koors),
- inflammasie van die pankreas (pankreatitis),
- allergiese reaksie van jou liggaam op sekere medikasie of infeksies (serumsiekte), wat koors, uitslag, gewrigspyn en swelling veroorsaak. Dit verbeter gewoonlik sodra die behandeling stop,
- levernekrose,
- pulmonale eosinofilie, fibroserende alveolitis siektes wat byvoorbeeld simptome soortgelyk aan asma veroorsaak,
- vernouing of blokkasie van bloedvate,
- hartprobleme (nadelige effek as gevolg van moontlike allergiese reaksie).

Vertel jou dokter as jy enige van die volgende opmerk:

Gereelde nuwe-effekte:

- naarheid (siek voel), braking (siek wees), verlies aan eetlus (anoreksie), diarree,
- uitslag op die plek van toediening,
- koors, brand van toedieningsplek,
- velsensitiwiteit vir sonlig,
- pynlike knoppe onder die vel.

Minder gereelde nuwe-effekte:

- persgrys verkleuring van die vel.

Neuwe-effekte met onbekende frekwensie:

- duiseligheid,
- hoofpyn,
- moegheid,
- lomerigheid,
- probleme om aan die slaap te raak,
- depressie,
- swakheid, gevoelloosheid en pyn in die hande en voete,
- visieversteurings of verlies aan visie,
- spin sensasie (vertigo),
- voel ontkoppel van die werklikheid (psigosos),
- verswakte balans of koördinasie (ataksie). Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van nuwe-effekte

As jy nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA webwerf gevind word. Deur nuwe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van SILVOBLAZE OTC.

5. Hoe om SILVOBLAZE OTC te bewaar

- Berg alle medisyne buite bereik van kinders.
- Berg by of onder 25 °C. Beskerm teen lig.
- Gee alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat SILVOBLAZE OTC bevat:

Elke gram bevat 10 mg silwer sulfadiasien. Die ander bestanddele is arachis-olie (gehidrogeneerd), setielalkohol, polisorbataat 60, gesuiwerde water, propieleenglikol, metielparaben, propielhidroksibensoaat. Preservermiddels: metielhidroksibensoaat (0,15 % m/m) en propylhidroksibensoaat (0,05 % m/m).

Hoe SILVOBLAZE OTC lyk en inhoud van die verpakking

SILVOBLAZE OTC is 'n reuklose, wit homogene room.

SILVOBLAZE OTC word verpak in 'n 50 g aluminium membraan geslote buis met voorafgedrukte buitebedekking en epoksie fenoliese voering. Die doppie is 'n koniese LDPE (laedigheid poliëteleen) skroefdoop met 'n deurstekpeyn vir die membraan.

Houer van registrasiesertifikaat

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Hierdie pamflet is laas hersien

25 Februarie 2025

Registrasienommer

56/14.2/0749

Toegang tot die ooreenstemmende professionele inligting

Die Professionele Inligtingspamflet is beskikbaar by Biotech Laboratories (Edms.) Bpk. Om 'n digitale kopie aan te vra, stuur asseblief 'n e-pos na info@biotechlabs.co.za.