SCHEDULING STATUS

S4

VERSATIS 5 % Medicated Plaster
Lidocaine

Read all of this leaflet carefully before you start using VERSATIS 5 % Medicated Plasters

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- **VERSATIS 5 %** Medicated Plasters 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 VERSATIS 5 % is and what it is used for
2. What you need to know before you use VERSATIS 5 %
3. How to use VERSATIS 5 %
4. Possible side effects
5. How to store VERSATIS 5 %
6. Contents of the pack and other information

1. What VERSATIS 5 % is and what it is used for

VERSATIS 5 % contains lidocaine, a local analgesic, which works by reducing the pain in your skin.

You have been given **VERSATIS 5 %** to treat a painful skin condition called post-herpetic neuralgia. After you have had shingles, post herpetic neuralgia may develop due to damage to the nerves in your skin. It is characterized by burning, shooting or stabbing pain which can last for a long time.

2. What you need to know before you use VERSATIS 5 %

Do not use **VERSATIS 5 %**

- If you are hypersensitive (allergic) to lidocaine or any of the other ingredients of **VERSATIS 5 % (**listed in section 6**).**
- If you have had an allergic reaction to other products which are similar to lidocaine, such as bupivacaine, etidocaine, mepivacaine or prilocaine.

Date of approval: 10 February 2025

Warnings and precautions

Take special care with VERSATIS 5 %:
If you have severe liver disease, or severe heart problems, or severe kidney problems, you should talk to your doctor before using **VERSATIS 5 %.**
VERSATIS 5 % should not be used on injured skin or open wounds. It should only be used on the areas of skin after the shingles has healed. It should not be used on or near the eyes or mouth.
Children and adolescents
VERSATIS 5 % has not been studied in patients under 18 years of age. Therefore, it is not recommended for use in this patient population.

Other medicines and VERSATIS 5 %
Always tell your health care provider if you are taking, any other medicine.
(This includes complementary or traditional medicines.)
If you are taking medicines on a regular basis, concomitant use of **VERSATIS 5 %** may cause undesirable interactions.
Absorption of lidocaine from the skin is normally low, the plaster must be used with caution if you are taking certain heart medicines e.g. tocainide, mexiletine, and other local anaesthetics as the risk of additive effects cannot be excluded

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before applying **VERSATIS 5 %** onto the skin.

Driving and using machines
An effect of **VERSATIS 5 %** on the ability to drive and use machines is unlikely. Therefore, you may drive or operate machinery whilst using **VERSATIS 5 %.**

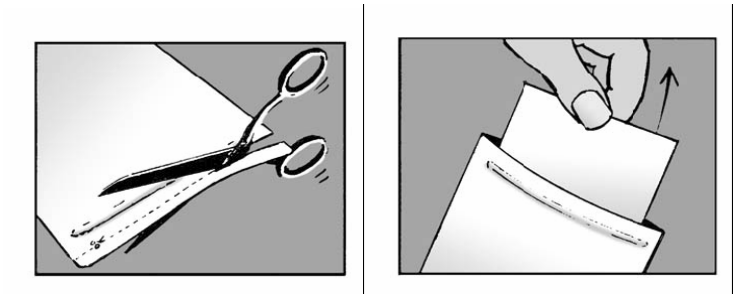
It is not always possible to predict to what extent **VERSATIS 5 %** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **VERSATIS 5 %** affects them.

VERSATIS 5 % contains propylene glycol, methyl parahydroxybenzoate and propyl parahydroxybenzoate
The plasters contain propylene glycol which may cause skin irritation. In addition, it contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions. The allergic reactions may sometimes occur after you have been using the plaster for some time.

3. How to use VERSATIS 5 %
Do not share medicines prescribed for you with any other person.
Always use **VERSATIS 5 %** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The usual daily dose is to use between one and three plasters of the size of the painful areas of your skin.
VERSATIS 5 % may be cut into smaller pieces to fit the affected area. You should not use more than 3 plasters at the same time.
The plasters should be removed after 12 hours of use, so that you have a 12-hour period with no plaster. You can choose to apply **VERSATIS 5 %** during the day or during the night.
Usually, you will feel some pain relief on the first day you use the plaster, but it may take up to 2 - 4 weeks until the full pain-relief effect of **VERSATIS 5 %** is seen. If after that time you still have a lot of pain, please talk to your doctor.
Your doctor will check how well **VERSATIS 5 %** is working at regular intervals.
Before you apply VERSATIS 5 % on the affected area

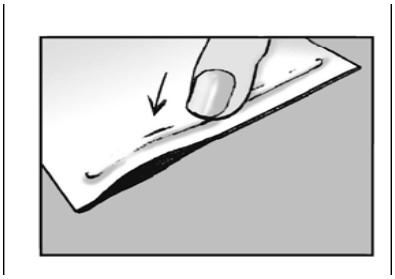
- If the painful area of skin has hairs on it, you can cut the hairs off using scissors. Do not shave them off.
- The skin should be clean and dry.
- Creams and lotions may be used on the affected skin during the period when you are not wearing the plaster, but the skin should be clean and dry before the plaster is stuck onto your skin.
- If you have had a recent bath or shower, you should wait until your skin cools and is dry before using the plaster.

Sticking the plaster on
Step 1: open the sachet and remove one or more plasters



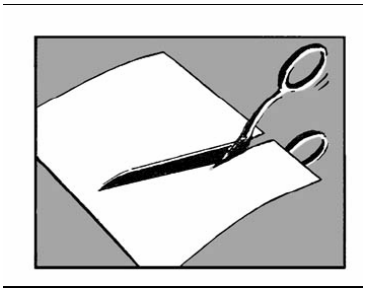
- tear open or cut the sachet along the dotted line
- when using scissors, be careful not to damage the plasters
- take out one or more plasters depending on the size of the painful area on your skin.

Step 2: close the sachet



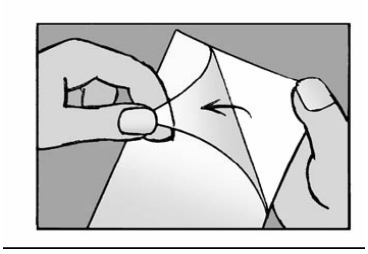
- close the sachet tightly after use
- the plaster contains water and will dry out if the sachet is not closed properly.

Step 3: cut the plaster, if necessary



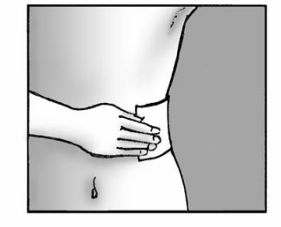
- if required, cut the plaster to the required size to fit the painful area of skin before removing the liner.

Step 4: remove the liner



- remove the transparent liner from the plaster
- try not to touch the sticky part of the plaster.

Step 5: apply the plaster and press it firmly onto the skin



- apply up to three plasters to the painful area of skin
- press the plaster onto your skin
- press for at least 10 seconds to make sure the plaster sticks firmly
- make sure that all of it sticks to your skin, including the edges.

Leave the plaster on for 12 hours only



It is important that **VERSATIS 5 %** is in contact with your skin for only 12 hours. For example, if you have more pain at night you might want to apply the plaster at 7 pm in the evening and remove it at 7 am in the morning.
If you have more pain during the day than at night you might want to apply **VERSATIS 5 %** at 7 am in the morning and remove it at 7 pm in the evening.

Bathing, showering and swimming
If at all possible, contact with water should be avoided whilst using **VERSATIS 5 %.** Bathing, showering or swimming can be done in the time period when you are not wearing the plaster. If you have had a recent bath or shower, you should wait until your skin cools and is dry before using the plaster.
If the plaster comes off
Very rarely the plaster might fall off or come unstuck. If it does, try sticking it back on the same area. If it does not stay on, remove it and put a new plaster on the same area.
If you forget to remove the plaster after 12 hours
As soon as you remember, remove the old plaster. A new plaster can be used again after 12 hours.
If you forget to use VERSATIS 5 %
After the 12-hour period with no plaster, if you have forgotten to use a new plaster, you should stick on a new plaster as soon as you remember.
Do not use double the number of plasters to make up for forgotten individual doses.

If you use more plasters than you should
If you use more plasters than necessary or wear them for too long, this may increase the risk of getting side effects.
If you have any further questions on the use of this product, ask your doctor or pharmacist.
In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Do not exceed the recommended dose.

How to remove and dispose of VERSATIS 5 %
When changing the plaster, remove the old plaster slowly. If it does not come off easily, you can soak it in warm water for a few minutes before removing the plaster.
Used plasters still contain active ingredient, which may be harmful to others. Fold the used plasters in half, with the sticky sides together and throw them away so that they are out of the reach of children and pets.

You should follow local guidelines for domestic waste when throwing away used or unused plasters. Ask your pharmacist how to dispose of medicines no longer required. Do not flush them down the toilet.

4. Possible side effects

VERSATIS 5 % can cause side effects.

Not all side effects reported for VERSATIS 5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **VERSATIS 5 %**, please consult your healthcare provider for advice.

If irritation or burning sensation occurs whilst you are using **VERSATIS 5 %**, it should be removed. The area of irritation should remain plaster free until the irritation stops.

Frequent side effects which may affect more than 1 person in 10 are listed below.

These include skin conditions at or around the site of plaster application, which may include redness, rash, itching, burning, dermatitis, and small blisters.

Less frequent side effects which may affect between 1 person in 100 and 1 in 1 000 are listed below.

Skin injury and skin wounds.

Side effects which may affect less than 1 person in 10 000 are listed below.

Open wound, severe allergic reaction and allergy.

VERSATIS 5 % may cause methaemoglobinaemia (rare blood disorder).

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><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 **VERSATIS 5 %**.

Alternatively side effects can be reported to Adcock Ingram Pharmacovigilance department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134.

5. How to store VERSATIS 5 %

- Store at or below 25 °C.
- Store the plasters in the original sachet, and close the sachet tightly after first opening. After opening the sachet, the plasters should be used within 14 days.
- Do not use **VERSATIS 5 %** after the expiry date that is stated on the sachet and carton. The expiry date refers to the last day of that month.
- Do not use **VERSATIS 5 %** if you notice that the sachet has been damaged. If this has occurred, the plasters may dry out and become less sticky.

- Do not refrigerate or freeze.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What VERSATIS 5 % contains

The active substance is 700 mg (5 % *m/m*) lidocaine in an aqueous adhesive base (50 mg lidocaine per gram adhesive base).
The other ingredients are:
Self-Adhesive Layer: Aluminium glycinate, carmellose sodium (E466), disodium edetate, gelatin, glycerol, heavy kaolin, liquid sorbitol (E420), polyacrylic acid, polyvinyl alcohol, propylene glycol (E1520), purified water, sodium polyacrylate, tartaric acid (E334), urea.
Backing fabric and release liner: polyethylene terephthalate (PET).
Preservatives:
Methyl parahydroxybenzoate 0,1 % *m/m*
Propyl parahydroxybenzoate 0,05 % *m/m*

What VERSATIS 5 % looks like and contents of the pack

The medicated plaster is 14 cm long and 10 cm wide. It is a white to pale yellow polymeric adhesive material with a faint characteristic odour, spread on one side of non-woven fabric, and covered with a plastic film. The non-woven fabric is embossed “Lidocaine 5 %”.
The plasters are packed in re-sealable white sachets, each containing 5 plasters.
Each carton contains 5, 10, or 30 plasters packed in 1, 2, or 6 sachets, respectively.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand,
South Africa
Customer Care: 0860 ADCOCK / 232625

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Registration number

43/3.2.3/0382

SKEDULERINGSTATUS

S4

VERSATIS 5 % Medisinale Pleister
Lidokaïen

Lees hierdie hele biljet noukeurig deur voordat u VERSATIS 5 % Medisinale Pleisters begin gebruik

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **VERSATIS 5 %** Medisinale Pleisters is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

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

1. Wat VERSATIS 5 % is en waarvoor dit gebruik word

VERSATIS 5 % bevat lidokaïen, 'n plaaslike pynstiller, wat werk deur die pyn in u vel te verminder.

U het **VERSATIS 5 %** ontvang om 'n pynlike veltoestand genaamd post-herpetiese neuralgie te behandel. Nadat u gordelroos gehad het, kan post-herpetiese neuralgie ontwikkel as gevolg van skade aan die senuwees in u vel. Dit word gekenmerk deur brand-, skiet- of steekpyn wat lank kan duur.

2. Wat u moet weet voordat u VERSATIS 5 % gebruik

Moenie **VERSATIS 5 %** gebruik nie

- Indien u hipersensitief (allergies) is vir lidokaïen of enige van die ander bestanddele van **VERSATIS 5 %** (gelys in afdeling 6).
- Indien u 'n allergiese reaksie gehad het op ander produkte wat soortgelyk is aan lidokaïen, soos bupivakaïen, etidokaïen, mepivakaïen of prilokaïen.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met VERSATIS 5 %:

Indien u ernstige lewersiekte, of ernstige hartprobleme, of ernstige nierprobleme het, moet u u dokter raadpleeg voordat u **VERSATIS 5 %** gebruik.

VERSATIS 5 % moet nie op beseerde vel of oop wonde gebruik word nie. Dit moet slegs op die velareas gebruik word nadat die gordelroos genees het. Dit moet nie op of naby die oë of mond gebruik word nie.

Kinders en adolessente
VERSATIS 5 % is nie by pasiënte jonger as 18 jaar bestudeer nie. Daarom word dit nie aanbeveel vir gebruik in hierdie pasiëntpopulasie nie.

Ander medisyne en VERSATIS 5 %
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem.
(Dit sluit komplementêre of tradisionele medisyne in.)
Indien u medisyne op 'n gereelde basis neem, kan gelyktydige gebruik van **VERSATIS 5 %** ongewenste interaksies veroorsaak.
Absorpsie van lidokaïen uit die vel is normaalweg laag, die pleister moet versigtig gebruik word indien u sekere hartmedisyne gebruik, bv. tokainied, meksiletien, en ander lokale verdowers, aangesien die risiko vir meegaande effekte nie uitgesluit kan word nie.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink dat u dalk swanger is of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat **VERSATIS 5 %** op die vel toegedien word.

Bestuur en gebruik van masjinerie
'n Effek van **VERSATIS 5 %** op die vermoë om te bestuur en masjiene te gebruik is onwaarskynlik. Daarom mag u bestuur of masjinerie gebruik terwyl u **VERSATIS 5 %** gebruik.

Dit is nie altyd moontlik om te voorspel in watter mate **VERSATIS 5 %** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle bewus is van die mate waartoe **VERSATIS 5 %** hulle beïnvloed nie.

VERSATIS 5 % bevat propileenglikol, metielparahidroksibensoaat en propielparahidroksibensoaat
Die pleisters bevat propileenglikol wat velirritasie kan veroorsaak. Daarbenewens bevat dit metielparahidroksibensoaat en propiellparahidroksibensoaat, wat allergiese reaksies kan veroorsaak. Die allergiese reaksies kan soms voorkom nadat u die pleister vir 'n geruime tyd gebruik het.

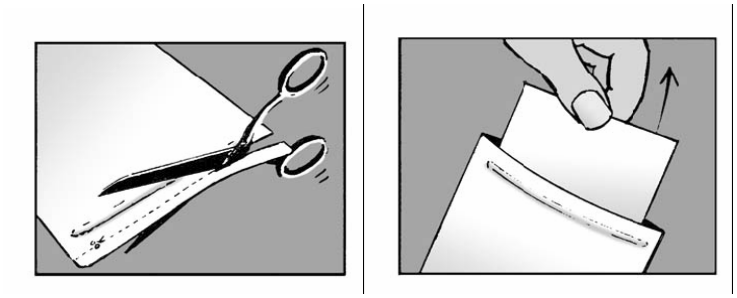
3. Hoe om VERSATIS 5 % te gebruik
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Gebruik altyd **VERSATIS 5 %** presies soos u dokter u ingelig het. U moet met u dokter of apteker bevestig indien u nie seker is nie.

Die gewone daaglikse dosis is om tussen een en drie pleisters, van die grootte van die pynlike areas van u vel, te gebruik.
VERSATIS 5 % kan in kleiner stukkies gesny word om oor die aangetaste area te pas. U moet nie meer as 3 pleisters gelyktydig gebruik nie.
Die pleisters moet na 12 uur se gebruik verwyder word, sodat u 'n tydperk van 12 uur sonder pleisters het. U kan kies om **VERSATIS 5 %** gedurende die dag of gedurende die nag toe te dien.
Gewoonlik sal u 'n mate van pynverligting ervaar op die eerste dag wat u die pleister gebruik, maar dit kan tot 2-4 weke neem totdat die volle pynverligtingseffek van **VERSATIS 5 %** ervaar word. Indien u na daardie tyd nog baie pyn het, raadpleeg asseblief u dokter.
U dokter sal gereeld bepaal hoe goed **VERSATIS 5 %** werk.

Voordat u VERSATIS 5 % op die aangetaste area toedien

- Indien die pynlike area van die vel hare op het, kan u die hare met 'n skêr afsny. Moenie hulle afskeer nie.
- Die vel moet skoon en droog wees.
- Rome en vloeiroom kan op die aangetaste vel gebruik word gedurende die tydperk wanneer u nie die pleister dra nie, maar die vel moet skoon en droog wees voordat die pleister op u vel vasgeplak word.
- Indien u onlangs 'n bad of stort geneem het, moet u wag totdat u vel afkoel en droog is voordat u die pleister gebruik.

Om die pleister op te plak
Stap 1: maak die sakkie oop en verwyder een of meer pleisters



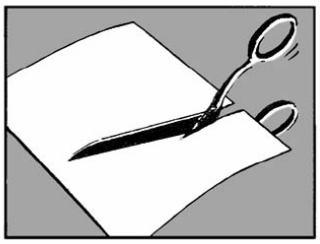
- Skeur oop of sny die sakkie langs die stippellyn
- Indien u 'n skêr gebruik, moet u versigtig wees om nie die pleisters te beskadig nie
- Haal een of meer pleisters uit, afhangende van die grootte van die pynlike area op u vel.

Stap 2: maak die sakkie toe



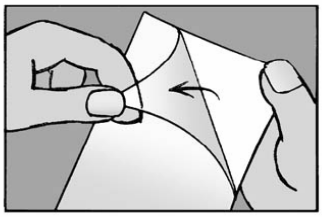
- Maak die sakkie styf toe na gebruik
- Die pleister bevat water en sal uitdroog indien die sakkie nie behoorlik toegemaak is nie.

Stap 3: sny die pleister, indien nodig



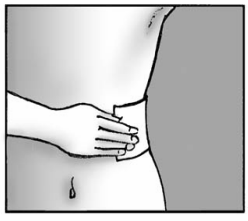
- Indien nodig, sny die pleister tot die vereiste grootte om by die pynlike velarea te pas voordat die voering verwyder word.

Stap 4: verwyder die voering



- Verwyder die deursigtige voering van die pleister
- Probeer om nie aan die taai gedeelte van die pleister te raak nie.

Stap 5: wend die pleister aan en druk dit stewig op die vel vas



- Wend tot drie pleisters aan op die pynlike area van die vel
- Druk die pleister op u vel
- Druk vir ten minste 10 sekondes om seker te maak dat die pleister stewig vassit
- Maak seker dat die hele pleister aan u vel kleef, insluitend die rande.

Laat die pleister slegs vir 12 uur aan



Dit is belangrik dat **VERSATIS 5 %** slegs vir 12 ure in kontak met u vel is. Byvoorbeeld, indien u meer pyn in die nag het, wil u dalk die pleister om 7 nm in die aand aanwend en dit om 7 vm in die oggend verwyder.
Indien u meer pyn gedurende die dag as in die nag het, wil u dalk **VERSATIS 5 %** om 7 vm in die oggend toedien en dit om 7 nm in die aand verwyder.

Bad, stort en swem
Indien enigsins moontlik, moet kontak met water vermy word terwyl **VERSATIS 5 %** gebruik word. Om te bad, stort of swem is moontlik in die tydperk wanneer u nie die pleister dra nie. Indien u onlangs 'n bad of stort gehad het, moet u wag totdat u vel afkoel en droog is voordat u die pleister gebruik.

Indien die pleister los kom
Baie selde kan die pleister afval of los kom. Indien dit wel gebeur, probeer om dit weer op dieselfde area te plak. Indien dit nie aanbly nie, verwyder dit en plaas 'n nuwe pleister op dieselfde area.

Indien u vergeet om die pleister na 12 ure te verwyder
Sodra u onthou, verwyder die ou pleister. 'n Nuwe pleister kan na 12 ure weer gebruik word.

Indien u vergeet om VERSATIS 5 % te gebruik
Na die periode van 12 uur sonder ‘n pleister, indien u vergeet het om 'n nuwe pleister te gebruik, moet u 'n nuwe pleister plak sodra u onthou.
Moenie dubbel die aantal pleisters gebruik om vergete individuele dosisse op te maak nie.

Indien u meer pleisters gebruik as wat u moes
Indien u meer pleisters gebruik as wat nodig is of dit te lank dra, kan dit die risiko verhoog om newe-effekte te kry.
Indien u enige verdere vrae het oor die gebruik van hierdie produk, raadpleeg u dokter of apteker.
In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Moenie die aanbevole dosis oorskry nie.

Hoe om VERSATIS 5 % te verwyder en weg te gooi
Wanneer u die pleister vervang, moet u die ou pleister stadig verwyder. Indien dit nie maklik afkom nie, kan u dit 'n paar minute in warm water week voordat u die pleister verwyder.
Gebruikte pleisters bevat steeds aktiewe bestanddeel wat skadelik vir ander kan wees. Vou die gebruikte pleisters in die helfte, met die taai kante aanmekaar en gooi dit weg waar dit buite bereik van kinders en troeteldiere is.
U moet plaaslike riglyne vir huishoudelike afval volg wanneer u gebruikte of ongebruikte pleisters weggooi. Vra u apteker hoe om van medisyne ontslae te raak wat nie meer nodig is nie. Moet dit nie in die toilet afspoel nie.

4. Moontlike newe-effekte
VERSATIS 5 % kan newe-effekte veroorsaak.
Nie alle newe-effekte wat vir VERSATIS 5 % aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u **VERSATIS 5 %** gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.
Indien irritasie of brandende sensasie voorkom terwyl u **VERSATIS 5 %** gebruik, moet dit verwyder word. Die area van irritasie moet pleistervry bly totdat die irritasie stop.

Gereelde newe-effekte wat meer as 1 uit 10 persone kan beïnvloed, word hieronder gelys.
Dit sluit in veltoestande by of rondom die plek van pleistertoediening, wat rooiheid, uitslag, jeukerigheid, brand, dermatitis en klein blase kan insluit.

Minder gereelde newe-effekte wat tussen 1 uit 100 en 1 uit 1 000 persone kan affekteer, word hieronder gelys.
Velbesering en velwonde.

Newe-effekte wat minder as 1 uit 10 000 persone kan affekteer, word hieronder gelys.
Oop wond, ernstige allergiese reaksie en allergie.

VERSATIS 5 % kan methemoglobinemie (seldsame bloedafwyking) veroorsaak.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **VERSATIS 5 % te verskaf**.
Alternatiewelik kan newe-effekte by Adcock Ingram se Farmaseutiese Monitering-afdeling aangemeld word per e-pos aan Adcock.Aereports@adcock.com, faks na +27 86 553 0128

of skakel 011 635 0134.

5. Hoe om VERSATIS 5 % te bêre

- Bêre teen of benede 25 °C.
- Bêre die pleisters in die oorspronklike sakkie en maak die sakkie styf toe na die eerste opening. Nadat die sakkie oopgemaak is, moet die pleisters binne 14 dae gebruik word.
- Moenie **VERSATIS 5 %** gebruik ná die vervaldatum wat op die sakkie en kartonhouer aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.
- Moenie **VERSATIS 5 %** gebruik indien u agterkom dat die sakkie beskadig is nie. Indien dit gebeur het, kan die pleisters uitdroog en minder taai word.
- Moenie in die yskas bêre of vries nie.
- Neem alle ongebruikte medisyne terug na u apteker
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie

BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS

6. Inhoud van die verpakking en ander inligting

Wat VERSATIS 5 % bevat

Die aktiewe bestanddeel is 700 mg (5 % *m/m*) lidokaïen in 'n waterige kleefbasis (50 mg lidokaïen per gram kleefbasis).

Die ander bestanddele is:

Self-klewende laag: Aluminiumglisinaat, natriumkarmellose (E466), dinatriumedetaat, gelatien, gliserol, swaar kaolien, vloeibare sorbitol (E420), poliakrielsuur, polivinielalkohol, propileenglikol (E1520), gesuiwerde water, natriumpoliakrilaat, wynsteensuur (E334), ureum.

Ondersteuningsmateriaal en vrystellingsvoering: poliëtileentereftalaat (PET).

Preserveermiddels:

Metielparahidroksibensoaat 0,1 % *m/m*

Propielparahidroksibensoaat 0,05 % *m/m*

Hoe VERSATIS 5 % lyk en die inhoud van die verpakking

Die medisinale pleister is 14 cm lank en 10 cm breed. Dit is 'n wit tot liggeel polimeriese kleefmateriaal met 'n dowwe kenmerkende reuk, versprei aan die een kant van nie-geweefde materiaal en bedek met 'n plastiekfilm. Die nie-geweefde stof is bedruk met "Lidocaine 5 %".

Die pleisters is verpak in hersluitbare wit sakkies, wat elk 5 pleisters bevat.

Elke kartonhouer bevat 5, 10 of 30 pleisters wat onderskeidelik in 1, 2 of 6 sakkies verpak is.

Nie alle verpakkingsgroottes mag dalk bemark word nie.

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Houer van Sertifikaat van Registrasie
Adcock Ingram Limited
New Road 1,
Erand Gardens,
Midrand,
Suid-Afrika
Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
10 Februarie 2025

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