Front Side 335 x 350 mm

355 mm

VENTSOL INHALER 100 µg
PM00460501

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

VENTSOL INHALER 100 µg/actuation (Aerosol)
Salbutamol sulfate
Sugar free.

Read all of this leaflet carefully before you start taking VENTSOL INHALER 100 µg
- Keep this leaflet. You may need to read it again.
- Do not share **VENTSOL INHALER 100 µg** with any other person.
- Ask your healthcare 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 **VENTSOL INHALER 100 µg** is and what it is used for
2. What you need to know before you take **VENTSOL INHALER 100 µg**
3. How to take **VENTSOL INHALER 100 µg**
4. Possible side effects
5. How to store **VENTSOL INHALER 100 µg**
6. Contents of the pack and other information

1. What VENTSOL INHALER 100 µg is and what it is used for

VENTSOL INHALER 100 µg belongs to a group of medicines called fast acting bronchodilators. Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out. They help to relieve chest tightness, wheezing and cough. **VENTSOL INHALER 100 µg** is an inhaler used to ease breathing problems in asthma and other chest illnesses.

2. What you need to know before you take VENTSOL INHALER 100 µg

Do not use VENTSOL INHALER 100 µg
- If you are hypersensitive (allergic) to salbutamol or any of the other ingredient of **VENTSOL INHALER 100 µg,** listed in **section 6**.
- If you have unexpected early labour (premature labour) or bleeding in initial stage of pregnancy,
- If you are taking medicines called beta-blockers (e.g. propranolol).

Warnings and precautions
Tell your doctor before taking **VENTSOL INHALER 100 µg**:
- If you have an overactive thyroid gland.
- If you suffer high blood pressure.
- If you have a history of heart problems such as an irregular or fast heartbeat or angina.
- If you are taking other medicines for asthma.
- If you have asthma as you may experience an acute asthma attack.
- If you feel shortness of breath, tightness in the chest and wheezing.
- If you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- If you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

After using your **VENTSOL INHALER 100 µg**:
- If your breathing or wheezing gets worse straight after using **VENTSOL INHALER 100 µg**, stop using it immediately and tell your doctor as soon as possible.
- If the relief of wheezing or chest tightness is not as good as usual or does not last for as long as usual, tell your doctor as soon as possible. Your chest condition may be getting worse and you may need an extra medicine.
- If you need to use your **VENTSOL INHALER 100 µg** much more often than normal, see your doctor as soon as possible.

Other medicines and VENTSOL INHALER 100 µg
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Inform your doctor or pharmacist if:
- You are due to have or have recently been given an anaesthetic such as with cyclopropane, halothane or other halogenated anaesthetics.
- You are taking cardiac glycosides (to treat heart failure)
- You are taking phenylephrine (to treat stuffy nose, cold or other breathing illnesses)
- You are taking isoproterenol (to treat heart attack)
- You are taking quinidine or tricyclic antidepressants (to treat depression).
- You are taking beta-blocking medicines such as propranolol (to treat angina and high blood pressure)
- You are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.

The amount of drug delivered to the lungs will depend on patient factors, such as inspiratory flow and peak inspiratory flow (PIF) through the delivery system, which may vary for asthma, COPD, and other patient populations.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, or plan to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before using **VENTSOL INHALER 100 µg**.

Driving and using machines
VENTSOL INHALER 100 µg is not likely to affect you being able to drive or use any tools or machines.

3. How to use VENTSOL INHALER 100 µg

- Do not share medicines prescribed for you with any other person. Always use **VENTSOL INHALER 100 µg** exactly as your doctor or pharmacist has told you.
- Check with your doctor or pharmacist if you are not sure.

VENTSOL INHALER 100 µg must be breathed in through the mouth. Shake the inhaler before use. The label on it will usually tell you how much to take and how often. If you are not sure ask your doctor, nurse or pharmacist.
You must not inhale more puffs, or use your inhaler more often, than the doctor told you to. Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.
The usual dose is one [100 µg (micrograms)] or two (2 x 100 µg (micrograms)] puffs, repeated every four hours if required.

Do not exceed the recommended dose.
If you have the impression that the effect of **VENTSOL INHALER 100 µg** is too strong or too weak talk to your doctor or pharmacist.

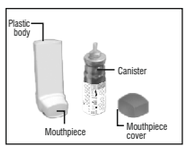
If you use more VENTSOL INHALER 100 µg than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
If you take a larger dose than recommended, you are more likely to get side effects, like a faster heartbeat, headaches, or hallucinations (seeing or hearing things which are not there). You may also feel shaky or notice changes in your behaviour such as restlessness or irritability.

If you forget to take VENTSOL INHALER 100 µg
If you forget to inhale a dose, just inhale the next dose when it is due, or before if you become wheezy. Do not take a double dose to make up for a forgotten dose.
Your doctor may have told you to use your inhaler regularly every day or only when you are wheezy or short of breath.

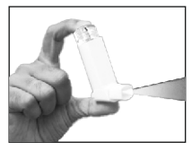
If you stop using VENTSOL INHALER 100 µg
Do not stop using **VENTSOL INHALER 100 µg** without consulting your doctor. If you stop using **VENTSOL INHALER 100 µg** abruptly, it may make your asthma worse.

HOW TO USE YOUR INHALER CORRECTLY

PARTS OF THE INHALER



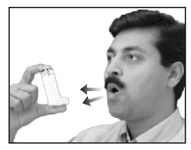
Testing your inhaler
Remove the mouthpiece cover by gently squeezing the sides of the cover. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.
Before using your inhaler for the first time, or if it has not been used for a week or more, "test fire" it, i.e. release one or two puffs into the air to make sure that it works.





Using your Inhaler
1) Remove the mouthpiece cover, and check that the mouthpiece is clean.

Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed. Hold the inhaler upright as shown with your thumb on the base. Place either one or two fingers on top of the canister.



2) Breathe out gently, through your mouth.

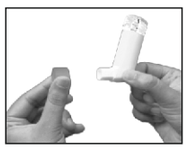


3) Place the mouthpiece of the inhaler in your mouth between your teeth and close your lips around it (Do not bite it).

Start breathing in slowly through your mouth. As you breathe in, press down the canister to release one dose while continuing to breathe in steadily and deeply.



4) Remove the inhaler from your mouth and hold your breath for 10 seconds, or for as long as it is comfortable. Breathe out slowly.

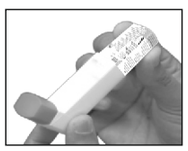


5) If another dose is required wait for at least one minute. Repeat steps 2 to 4. After use, replace the mouthpiece cover.

Important do not rush steps 3 to 4. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practice in front of mirror for the first few times. If you see "mist" coming from the top of the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.



Cleansing
It is essential to keep the plastic mouthpiece clean, to ensure proper functioning of the inhaler. Clean your inhaler at least once a week, as follows:



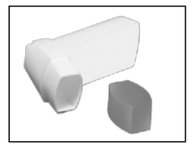
1) Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.



2) Immerse the plastic body and the mouthpiece cover in warm water. Do not put the metal canister in the water.



3) Next, rinse the plastic body and mouthpiece cover under running tap water.



4) Shake well to remove excess water. Leave to dry. Avoid the use of heat to dry the parts.

5) When the plastic body is dry, replace the canister and the mouthpiece cover correctly.

4. Possible side effects

VENTSOL INHALER 100 µg can have side effects.
Not all side effects reported for **VENTSOL INHALER 100 µg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop using **VENTSOL INHALER 100 µg** 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
- Severe rash or itching
- Sudden wheeziness or chest tightness
- Feeling faint and lightheaded, and collapse

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VENTSOL INHALER 100 µg.** 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:
- Bronchospasm (tightening of the muscles in the airways which causes wheezing).
- Mood changes (such as depression)
- Angina

These are all serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following:
Frequently occurring side effects:
- Feeling shaky (especially in the hands)
- Heart beats faster or stronger than usual
- Irregular heartbeat due to nervousness or illness
- Headache

Less frequent side effects:
- Allergic reactions such as constriction of the air passages of the lung, wheezing, swelling of the lower layer of skin.
- Decreased blood pressure.
- Changes in behaviour such as excitedness or agitation
- Nervousness and fear
- Lack of energy (fatigue), restlessness
- Weak muscles
- Confusion
- Hyperactivity and inability to concentrate
- Loss of sleep (insomnia)
- Chest pains due to heart problems
- Nausea and vomiting
- Mouth or throat irritation
- Increased cough or increased breathing difficulties
- An irregular, often rapid heart rate
- Feel aching, cramping or tiredness in the legs
- Feeling tired or exhausted for no reason
- Joint pain, muscle pain and discomfort, back pain or chest pain
- Difficulty in discharge of urine
- Difficulty in breathing
- Sweating
- Increased amount of saliva in the mouth.

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. This includes any possible side effects not listed in this leaflet. 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 or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **VENTSOL INHALER 100 µg.**

5. How to store VENTSOL INHALER 100 µg

Store at or below 30 °C.
Replace the mouthpiece cover firmly and snap it into position.
Protect from frost and direct sunlight.
The canister should not be punctured, broken or burnt even if it is apparently empty.
KEEP OUT OF REACH OF CHILDREN.

6. Contents of pack and other information

What VENTSOL INHALER 100 µg contains
The active ingredient is salbutamol sulfate.
The other ingredient is 1,1,1,2 Tetrafluoroethane (Propellant HFA 134a)

What VENTSOL INHALER 100 µg looks like and contents of the pack
VENTSOL INHALER 100 µg:
Pressurised metered dose inhaler containing suspension aerosol filled in aluminum canister fitted with suitable metered valve. There should be no sign of physical damage or leakage.

A 19 ml aluminium canister fitted with metered dispensing 50 µl nitrile valve crimped in place and a polypropylene actuator attached (dark blue coloured cap and light blue colour body), placed in a outer carton. Each Canister provides 200 inhalations.

Holder of Certificate of Registration and Manufacturer
Macleods Pharmaceuticals SA (Pty) Ltd
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
09 November 2022

Registration number
54/10.2.1/0234.233

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

335 mm

Back Side 335 x 355 mm

355 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS : S2

VENTSOL INHALER 100 µg/aandrywing (Aërosol)
Salbutamolsulfaat
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy VENTSOL INHALER 100 µg begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Moet nie **VENTSOL INHALER 100 µg** met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy meer inligting of raad benodig.
- Jy moet 'n dokter sien indien jou simptome vererger of nie verbeter nie.

Wat is in hierdie inligtingstuk
1. Wat **VENTSOL INHALER 100 µg** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **VENTSOL INHALER 100 µg** gebruik
3. Hoe om **VENTSOL INHALER 100 µg** te gebruik
4. Moontlike newe-effekte
5. Hoe om **VENTSOL INHALER 100 µg** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat VENTSOL INHALER 100 µg is en waarvoor dit gebruik word

VENTSOL INHALER 100 µg behoort aan 'n groep van medisyne wat vinnigwerkende brongodilators genoem word. Brongodilators help die lugweë in jou longe om oop te bly. Dit maak dit makliker vir lug om in en uit te beweeg. Hulle help om beklemmende borskas, hyg en hoes te verlig. **VENTSOL INHALER 100 µg** is 'n inhaleerder wat gebruik word om asemhalingsprobleme in asma en ander borskas siektes te verlig.

2. Wat jy behoort te weet voordat jy VENTSOL INHALER 100 µg gebruik

Moet nie VENTSOL INHALER 100 µg gebruik nie
- Indien jy hipersensitief (allergies) is vir salbutamol of enige van die ander bestanddele van **VENTSOL INHALER 100 µg**, gelys in **afdeling 6**.
- As jy onverwagte vroeë kraam (premature kraam) of bloeding in die aanvanklike stadium van swangerskap het,
- Indien jy medisyne neem, naamlik beta blokkeerders (bv. propranolol).

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter voordat jy **VENTSOL INHALER 100 µg** neem:
- Indien jy 'n ooraktiewe skildklier het
- Indien jy aan hoë bloeddruk ly.
- Indien jy 'n geskiedenis van hartprobleme soos 'n onreëlmatige of vinnige hartklop of angina het.
- Indien jy ander medisyne vir asma neem.
- Indien jy asma het aangesien jy 'n akute asma-aanval kan ervaar.
- Indien jy kort van asem, benoudheid in die bors en asemgefluit voel.
- Indien jy xantienderivate (soos teofillien) of steroïede neem om asma te behandel.
- Indien jy watertablette (diuretika) gebruik, wat soms gebruik word om hoë bloeddruk of 'n hartkwaal te behandel.

Nadat jy jou **VENTSOL INHALER 100 µg** gebruik het**:**
- As jou asemhaling of gehyg erger raak direk nadat jy **VENTSOL INHALER 100 µg** gebruik het, hou onmiddelik op om dit te gebruik en vertel jou dokter so gou as moontlik.
- Wanneer die verligting van gehyg of benoudheid in die bors nie so effektief soos gewoonlik is nie, of nie so lank soos gewoonlik hou nie, vertel jou dokter so gou as moontlik. Jou borskastoestand kan dalk erger word en jy sal dalk ekstra medisyne nodig hê.
- Indien jy jou **VENTSOL -INHALER 100 µg** baie meer gereeld as normaalweg moet gebruik, sien jou dokter so gou as moontlik.

Ander medisyne en VENTSOL INHALER 100 µg
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Stel jou dokter of apteker in kennis indien:
- Jy 'n narkose middel soos met siklopropaan, halotaan of ander gehalogeneerde narkose middels moet kry of onlangs toegedien is.
- Jy hartglikosiede neem (om hartversaking te behandel)
- Jy fenielefrien neem (om toe neus, verkoue of ander asemhalingsiektes te behandel)
- Jy isoproterenol neem (om hartaanval te behandel)
- Jy kinidien of trisikliese antidepressante neem (om depressie te behandel).
- Jy beta blokkerende medisyne soos propranolol neem (om angina en hoë bloeddruk te behandel)
- Jy xantienderivate (soos teofillien) of steroïede neem om asma te behandel.

Die hoeveelheid van geneesmiddel wat aan die longe gelewer word, sal afhang van pasiëntfaktore, soos inspiratoriese vloei en piek inspiratoriese vloei (PIF) deur die afleweringstelsel, wat kan verskil vir asma, COPD en ander pasiëntpopulasies.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, of van plan is om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **VENTSOL INHALER 100 µg** gebruik.

Bestuur en gebruik van masjinerie
VENTSOL INHALER 100 µg sal waarskynlik nie jou vermoë om te bestuur of enige gereedskap of masjiene te gebruik, beïnvloed nie.

3. Hoe om VENTSOL INHALER 100 µg te gebruik

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd **VENTSOL INHALER 100 µg** presies soos jou dokter of apteker vir jou voorgeskryf het.
- Bevestig met jou dokter of apteker indien jy nie seker is nie.

VENTSOL INHALER 100 µg moet deur die mond ingeasem word. Skud die inhaleerder voor gebruik. Die etiket daarop sal jou gewoonlik vertel hoeveel om te neem en hoe gereeld. Indien jy nie seker is nie, vra jou dokter, verpleegkundige of apteker.
Jy moet nie meer inhalasies inasem of jou inhaleerder meer gereeld gebruik as wat die dokter jou beveel het nie. Jou dokter het moontlik vir jou aanbeveel om meer as hierdie as 'n noodbehandeling te neem, indien jou gehyg of asemhaling baie erg word. Dit is baie belangrik dat jy by jou dokter se instruksies hou oor hoeveel inhalasies om te neem en hoe gereeld om jou inhaleerder te gebruik. Die gewone dosis is een [100 µg (mikrogram)] of twee (2 x 100 µg (mikrogram)] inhalasies, herhaal elke vier uur indien nodig.

Moet nie die aanbevole dosis oorskry nie.
Indien jy die indruk het dat die effek van **VENTSOL INHALER 100 µg** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer VENTSOL INHALER 100 µg gebruik as wat jy behoort te neem:
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Indien jy 'n groter dosis neem as wat aanbeveel word, is jy meer geneig om newe-effekte te kry, soos 'n vinniger hartklop, hoofpyne of hallusinasies (sien of hoor dinge wat nie daar is nie). Jy kan ook bewerig voel of veranderinge in jou gedrag opmerk, soos rusteloosheid of prikkelbaarheid.

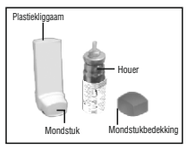
Indien jy vergeet om VENTSOL INHALER 100 µg te neem
Indien jy vergeet om 'n dosis te inhaleer, inhaleer net die volgende dosis wanneer jy dit behoort te doen, of vroeër indien jy hygend word. Moet nie 'n dubbele dosis neem om 'n vergete dosis in te haal nie.

Jou dokter het moontlik vir jou gesê om jou inhaleerder gereeld elke dag te gebruik of net wanneer jy hyg of kort van asem is.

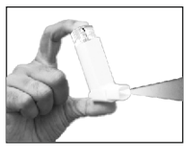
Indien jy ophou om VENTSOL INHALER 100 µg te neem
Moet nie ophou om **VENTSOL INHALER 100 µg** te gebruik sonder om jou dokter te raadpleeg nie. Indien jy skielik ophou om **VENTSOL INHALER 100 µg** te gebruik, kan dit jou asma laat vererger.

HOE OM JOU INHALEERDER KORREK TE GEBRUIK

DELE VAN DIE INHALEERDER

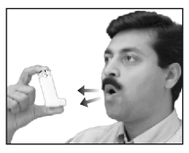


Toets jou inhaleerder
Verwyder die mondstukbedekking deur die kante van die bedekking versigtig te druk. Kyk binne en buite die inhaleerder, insluitend die mondstuk, vir die teenwoordigheid van los voorwerpe.
Voordat jy jou inhaleerder vir die eerste keer gebruik, of as dit vir 'n week of langer nie gebruik is nie, "toetsvuur" dit, d.w.s. spuit een of twee inhalasies in die lug om seker te maak dat dit werk.





Gebruik jou inhaleerder
1) Verwyder die mondstukbedekking en maak seker dat die mondstuk skoon is.
Skud die inhaleerder goed om te verseker dat enige los voorwerpe verwyder word en dat die inhoud van die inhaleerder eweredig gemeng word. Hou die inhaleerder regop soos aangedui met jou duim op die basis. Plaas een of twee vingers bo-op die houer.



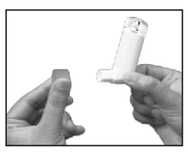
2) Asem versigtig uit, deur jou mond.



3) Plaas die mondstuk van die inhaleerder in jou mond tussen jou tande en maak jou lippe om dit toe (Moet nie daaraan byt nie).
Begin stadig deur jou mond inasem. Terwyl jy inasem, druk die houer af om een dosis vry te stel terwyl jy aanhou om reëlmatig en diep in te asem.



4) Verwyder die inhaleerder vanuit jou mond en hou jou asem vir 10 sekondes, of vir so lank as wat dit gemaklik is. Asem stadig uit.



5) Indien nog 'n dosis benodig word, wag vir ten minste een minuut. Herhaal stappe 2 tot 4. Na gebruik, plaas die mondstukbedekking terug.



Belangrik; moet nie stappe 3 tot 4 haas nie. Dit is belangrik dat jy so stadig as moontlik begin inasem net voor jy die dosis vrystel. Oefen die eerste paar keer voor die spieël. Wanneer jy "mis" vanuit die bokant van die inhaleerder of by die kante van jou mond sien uitkom, begin weer vanaf stap 1. Hierdie mis wat ontsnap dui op 'n verkeerde tegniek.

Reiniging
Dit is noodsaaklik om die plastiese mondstuk skoon te hou, om behoorlike funksionering van die inhaleerder te verseker. Maak jou inhaleerder ten minste een keer per week skoon, soos volg:



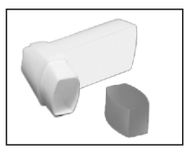
1) Trek die metaalhouer liggies uit die plastiese liggaam van die inhaleerder. Verwyder die bedekking van die mondstuk.



2) Dompel die plastiese liggaam en die mondstukbedekking in warm water. Moet nie die metaalhouer in die water plaas nie.



3) Spoel daarna die plastiese liggaam en mondstukbedekking onder lopende kraanwater uit.



4) Skud goed om oortollige water te verwyder. Laat droog word. Vermy die gebruik van hitte om die dele te droog.

5) Wanneer die plastiese liggaam droog is, plaas die houer en die mondstukbedekking korrek terug.

4. Moontlike newe-effekte

VENTSOL INHALER 100 µg kan newe-effekte hê.
Nie al die newe-effekte wat vir **VENTSOL INHALER 100 µg** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy hierdie medisyne neem, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **VENTSOL INHALER 100 µg** te gebruik en vertel onmiddellik jou dokter 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
- Erge uitslag of jeuk
- Skielike gehyg of benoude bors
- Voel flou en lighoofdig, en sak ineen

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **VENTSOL INHALER 100 µg** gehad. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.
Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Brongospasma (saamtrek van die spiere in die lugweë wat gehyg veroorsaak).
- Gemoedsveranderinge (soos depressie)
- Angina,

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese aandag.
Vertel jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- Voel bewerig (veral in die hande)
- Hart klop vinniger of sterker as gewoonlik
- Onreëlmatige hartklop as gevolg van senuweeagtigheid of siekte
- Hoofpyn

Minder gereelde newe-effekte:
- Allergiese reaksies soos vernouïng van die lugweë van die long, gehyg, swelling van die onderste laag van die vel.
- Verlaagde bloeddruk.
- Veranderinge in gedrag soos opgewondenheid of prikkelbaarheid
- Senuweeagtigheid en vrees
- Gebrek aan energie (vermoeidheid), rusteloosheid
- Swak spiere
- Verwarring
- Hiperaktiwiteit en onvermoë om te konsentreer
- Verlies aan slaap (slapeloosheid)
- Borskaspyne as gevolg van hartprobleme
- Naarheid en braking
- Mond- of keel irritasie
- Toename in hoes of toename in asemhalingsprobleme
- n Onreëlmatige, dikwels vinnige harttempo
- Voel pyn, krampe of moegheid in die bene
- Om sonder rede moeg of uitgeput te voel
- Gewrigspyn, spierpyn en ongemak, rugpyn of borskaspyn
- Probleme met uiskeiding van uriene
- Probleme om asem te haal
- Sweet
- Toename in hoeveelheid speeksel in die mond.

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **VENTSOL INHALER 100 µg**.

5. Hoe om VENTSOL INHALER 100 µg te bewaar

Bewaar by of benede 30°C.
Plaas die mondstukbedekking ferm terug en klik dit in posisie.
Beskerm teen ryp en direkte sonlig.
Die houer moet nie deurboor, gebreek of verbrand word nie, selfs al is dit klaarblyklik leeg.
HOU BUITE DIE BEREIK VAN KINDERS

6. Inhoud van die pak en ander inligting

Wat VENTSOL INHALER 100 µg bevat
Die aktiewe bestanddeel is salbutamolsulfaat.
Die ander bestanddeel is 1,1,1,2 Tetrafluoroëtaan (Dryfmiddel HFA 134a)

Hoe VENTSOL INHALER 100 µg lyk en inhoud van die pak
VENTSOL INHALER 100 µg:
Onder druk afgemete dosis inhaleerder wat suspensie aërosol bevat, gevul in aluminium houer toegerus met geskikte afgemete klep. Daar moet geen teken van fisiese skade of lekkasie wees nie.
'n 19 ml aluminium houer toegerus met afgemete dosis 50 µl nitrielklep in plek gekrimp en 'n polipropileen aktuator aangeheg (donkerblou gekleurde doppie en ligblou kleur liggaam), geplaas in 'n buitenste karton. Elke houer verskaf 200 inasemings.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika.

Hierdie inligtingstuk was laas hersien in
09 November 2022

Registrasienommer
54/10.2.1/0234.233

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

335 mm

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: VENTSOL INHALER 100 µg (Salbutamol Sulfate 100 mcg 200 metered actuations)	
2. Country: South Africa (Tender)	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 355 (L) x 335 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM00460501**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 41382 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Salbutamol\SA Private market\Tender\VENTSOL INHALER 100 µg PIL.cdr**
Approved By:	**17. Location: OXALIS**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	15/06/2026				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa (Tender)	PM00460501		