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PATIENT INFORMATION LEAFLET

25045

SCHEDULING STATUS: S2

TRISONE NS 50 Micrograms (µg)/Actuation
AQUEOUS NASAL SPRAY
Mometasone Furoate

Read all of this leaflet carefully because it contains important information for you
TRISONE NS is available without a doctor's prescription, for you to treat a mild illness/maintain your health. Nevertheless, you still need to use TRISONE NS carefully to get the best results from it.
- Keep this leaflet. You may need to read it again;
- Do not share TRISONE NS 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 TRISONE NS is and what it is used for
2. What you need to know before you use TRISONE NS
3. How to use TRISONE NS
4. Possible side effects
5. How to store TRISONE NS
6. Contents of the pack and other information

1. What TRISONE NS is and what it is used for
TRISONE NS contains mometasone furoate, one of a group of medicines called corticosteroids. When TRISONE NS is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked up or runny nose.

TRISONE NS is used to treat the symptoms of hay fever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 2 and older.

Hay fever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds, moulds and fungal spores. Perennial rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods.

TRISONE NS can also be used if you have a history of moderate to severe symptoms of seasonal allergic rhinitis. Prophylactic treatment with TRISONE NS is therefore recommended prior to the anticipated start of the pollen season.

2. What you need to know before you use TRISONE NS
Do not use TRISONE NS:
- If you are hypersensitive (allergic) to mometasone furoate or any of the other ingredients of TRISONE NS (listed in section 6);
- If you are pregnant or breastfeeding your baby;
- If your child is under the age of 2 years old;

Warnings and precautions
Take special care with TRISONE NS:
TRISONE NS should not be used:
- If you have an infection in your nose that is not being treated;
- If you have recently had an operation on your nose or have injured your nose. You should wait until your nose has healed before starting treatment with TRISONE NS.
- If you have ever had tuberculosis (an infectious bacterial disease characterized by the growth of nodules (tubercles) in the tissues, especially the lungs);
- If your immune system is not functioning well (if you have difficulty in fighting infection);
- If you have been diagnosed with any other bacterial, viral or fungal infection;
- If you develop a nasal infection while using TRISONE NS or continue to have persistent irritation to the nose or throat;
- If you are taking other corticosteroid medicines, either by mouth or by injection;
- If you suffer from a condition called cystic fibrosis (a hereditary disorder affecting the exocrine glands. It causes the production of abnormally thick mucus, leading to the blockage of the pancreatic ducts, intestines, and bronchi and often resulting in respiratory infection) or nasal polyps (soft, painless, noncancerous growths on the lining of your nasal passages or sinuses);
- If your eyes are irritated or still itching while using TRISONE NS, your doctor may recommend that you use other treatments together with TRISONE NS.

Children and adolescents
Do not use TRISONE NS in children younger than 2 years.

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side-effects, such as slowed growth rate in children.

It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified.

Other medicines and TRISONE NS
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Please inform your healthcare provider if you are currently taking any of the following medicines listed below:
- Other corticosteroid medicines used to treat allergies, either by mouth or injection. Your doctor may advise you to stop taking them once you begin using TRISONE NS. Few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, weakness and depression. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects, you should contact your doctor.
- Some medicines may increase the effects of TRISONE NS and your doctor may wish to monitor you carefully if you are taking these medicines (e.g., medicines used to treat HIV such as ritonavir and cobicistat).

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 healthcare provider for advice before taking this medicine.
You should not use TRISONE NS if you are pregnant or breastfeeding your baby.

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Driving and using machines
TRISONE NS may make you feel dizzy. If TRISONE NS affect you in this way do not drive, operate machinery or do anything that requires you to be alert.
It is not always possible to predict to what extent TRISONE NS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TRISONE NS affects you.

TRISONE NS contains benzalkonium chloride
TRISONE NS contains benzalkonium chloride, a preservative, which may cause nasal irritation.

3. How to use TRISONE NS
Do not share medicines prescribed for you with any other person.
Always use TRISONE NS exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

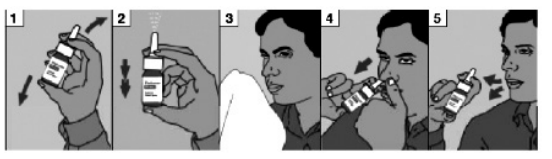
Adults and adolescents
The usual recommended dose for prevention and treatment of your symptoms is 2 sprays (50 µg/spray) into each nostril once daily (total dose 200 µg). Once your symptoms are controlled, you can reduce your dose to 1 spray into each nostril (total dose 100 µg) for maintenance.

If your symptoms are still inadequately controlled, your dose may be increased to a maximum daily dose of 4 sprays into each nostril once daily (total dose 400 µg). Dose reduction is recommended following control of your symptoms.

Children between the ages of 2 and 11 years
The usual recommended dose is 1 spray (50 µg/spray) into each nostril once daily (total dose 100 µg). Administration to young children should be aided by an adult.

Children younger than 2 years
The use of TRISONE NS in children younger than 2 years of age is not recommended.

Preparing TRISONE NS for use:



Step 1 and 2:
Prior to administration of the first dose, shake the container well before each use and actuate the pump approximately 10 times (until a uniform spray is obtained). If the pump is not used for 14 days or longer, re-prime the pump with approximately 2 actuations until a uniform spray is observed, before next use. No priming is needed subsequent to the initial priming is required with regular use.

Step 3:
Blow your nose gently.

Step 4:
Hold the bottle as shown. Place your finger on your nose to close one nostril and put the nozzle in your other nostril. Tilt your head forward and keep the bottle upright. Start to breathe in slowly through your nose and at the same time press down firmly on the collar of the bottle with your finger, which releases a spray of TRISONE NS.

Step 5:
Breathe out through your mouth. Repeat step 4 if more than one spray is required into the same nostril. Remove the nozzle from the nostril and breathe out through your mouth.

Repeat steps 4 to 5 for the other nostril. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.

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The bottle should be discarded after the labelled number of actuations have been used up or within 2 months of first use.

Your doctor, pharmacist or nurse will tell you how long your treatment with TRISONE NS will last. If you have the impression that the effect of TRISONE NS is too strong or too weak, tell your doctor, pharmacist or nurse.

If you take more TRISONE NS than you should
In the event of overdosage, consult your doctor, pharmacist or nurse. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TRISONE NS
Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects
TRISONE NS can have side effects.

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

If any of the following happens, stop using TRISONE NS 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 reaction to TRISONE NS. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Increase in pressure behind the eyes (glaucoma) causing visual disturbances;
- Damage to the part of the nose which separates the nostrils (septum).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor or healthcare provider if you notice any of the following:
Frequent side effects:
- Inflammation of the pharynx, causing a sore throat;
- Ear, nose and throat infections;
- Headache;
- Nose bleeds;
- Nasal burning;
- Nasal irritation;
- Nasal ulceration;
- Throat irritation;
- Sneezing.

Less frequent side effects:
- Nasal septum perforation;
- Coughing;
- Runny nose;
- Taste and smell disturbances;
- Nausea.

Frequency of side effects are unknown:
- Increased pressure within the eyeball, causing gradual loss of sight;
- Cataract, a medical condition in which the lens of the eye becomes progressively opaque, resulting in blurred vision;
- Blurred vision;
- Inflammation of the conjunctiva of the eye;
- Dry eyes;
- Inflammation of the mucous membrane of the nose;
- Inflammation of the sinuses;
- Dizziness;
- Skin rash.

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. 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 TRISONE NS.

5. How to store TRISONE NS
Store all medicines out of sight and reach of children.
Store at or below 25 ºC (room temperature).
Each bottle should be used within 2 months of first opening.
Do not use TRISONE NS after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.
Return all unused medicines 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 TRISONE NS contains
- The active substance is mometasone furoate. Each spray contains 50 micrograms of mometasone furoate, as the monohydrate.
- The other ingredients are benzalkonium chloride, glycerol, polysorbate 80, microcrystalline cellulose and carmellose sodium, citric acid monohydrate, sodium citrate, purified water.

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What TRISONE NS looks like
TRISONE NS is a white to off-white nasal spray suspension.
TRISONE NS is contained in a white, high density polyethylene bottle, that contains 10 g (60 actuations), 16 g (120 actuations) or 18 g (140 actuations) of product formulation, supplied with a metering pump and on which a nasal applicator with cap is fitted.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
Trinity Pharma (Pty) Ltd.
106 16th Road
Midrand
South Africa
1686

This leaflet was last revised in
N.A

Registration/Application number
50/21.5.1/0291

For professional information leaflet:
www.trinitypharma.co.za

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TRINITY PHARMA

Tel: 010 594 5610. Email: PV@kahmagroup.co.za

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PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS: S2

TRISONE NS 50 Mikrogram (µg)/Spuit
WATERIGE NEUSSPROEI
Mometasoonfuroaat

Lees die hele pamflet aandagtig deur voordat jy TRISONE NS gebruik
TRISONE NS is beskikbaar sonder 'n doktersvoorskrif om 'n ligte siektetoestand te behandel. Desondanks moet jy nogsteeds TRISONE NS met omsigtigheid gebruik om die beste resultate te verkry.
- Bewaar hierdie pamflet. Jy moet dit dalk weer lees.
- Moenie TRISONE NS met enige ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.
- Jy moet 'n dokter besoek indien jou simptome vererger of nie verbeter nie.

Wat is in hierdie pamflet
1. Wat TRISONE NS is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy TRISONE NS gebruik
3. Hoe om TRISONE NS te gebruik
4. Moontlike newe-effekte
5. Hoe om TRISONE NS te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat TRISONE NS is en waarvoor dit gebruik word
TRISONE NS bevat mometasoonfuroaat, 'n geneesmiddel wat deel vorm van 'n groep medisynes wat kortikosteroïedes genoem word. Wanneer TRISONE NS in die neus gespuit word, kan dit help met die verligting van inflammasie (swelling en irritasie van die neus), nies, jeuk en 'n verstopte- of loopneus.

TRISONE NS word gebruik vir die behandeling van hooikoors (ook genoem seisoenale allergiese rinitis) en aanhoudende rinitis in volwassenes en in kinders van 2 jaar en ouer.

Hooikoors, wat in sekere tye van die jaar voorkom, is 'n allergiese reaksie wat veroorsaak word deur die inaseming van stuifmeel van bome, grasse, onkruid en swamspore. Aanhoudende rinitis kom dwarsdeur die jaar voor en die simptome kan veroorsaak word deur 'n sensitiwiteit teenoor verskillende faktore, insluitend huisstofmyte, dierehare (of skilfers), vere en sekere voedselsoorte.

TRISONE NS kan ook gebruik word indien jy 'n geskiedenis het van matige tot ernstige simptome van seisoenale allergiese rinitis. TRISONE NS-behandeling word dus aanbeveel voor die verwagte aanvang van die stuifmeelseisoen.

2. Wat jy moet weet voordat jy TRISONE NS gebruik
Moenie TRISONE NS gebruik:
- Indien jy hipersensitief (allergies) is vir mometasoonfuroaat of vir enige van die ander bestanddele in TRISONE NS (gelys in afdeling 6);
- Indien jy swanger is of jou baba borsvoed;
- Indien jou kind jonger as 2 jaar oud is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met TRISONE NS:
TRISONE NS moet nie gebruik word:
- Indien jy 'n infeksie in jou neus het wat nie behandel word nie;
- Indien jy onlangs aan jou neus geopereer het of jou neus beseer het. Jy moet wag totdat jou neus ten volle genees het voordat jy TRISONE NS gebruik.
- Indien jy al ooit tuberkulose gehad het ('n aansteeklike bakteriese siekte wat gekenmerk word deur die groei van knoppe (tuberkels) in jou longweefsel);
- Indien jou immuunstelsel nie goed funksioneer nie (indien jy probleme ondervind om infeksies te beveg);
- Indien jy gediagnoseer is met enige ander bakteriële-, virale- of swaminfeksies;
- Indien jy 'n neusinfeksie opdoen of aanhoudende irritasie in die neus of keel ervaar terwyl jy TRISONE NS gebruik;
- Indien jy ander kortikosteroïedes neem, hetsy per mond of per inspuiting;
- Indien jy 'n toestand het wat sistiese fibrose genoem word ('n oorerflike afwyking wat die eksokriene kliere aantas. Dit veroorsaak die produksie van abnormale dik slym, wat lei tot die verstopping van die pankreaskanale, ingewande en brongi, wat dikwels longinfeksies tot gevolg het) of neus poliepe (sagte, pynlose, nie-kankeragtige groeisels aan die binnekant van jou neusholtes of sinusse);
- Indien jou oë geïrriteerd is of steeds jeuk terwyl jy TRISONE NS gebruik. Jou dokter kan aanbeveel dat jy moontlik ander behandelings saam met TRISONE NS moet gebruik.

Kinders en tieners
Moenie TRISONE NS gebruik in kinders jonger as 2 jaar oud nie.

Indien dit vir lang tydperke in hoë dosisse gebruik word, kan kortikosteroïed neussproeie sekere newe-effekte veroorsaak, soos vertraagde groeitempo in kinders.

Dit word aanbeveel dat die lengte van kinders wat langdurig met nasale kortikosteroïedes behandel word, gereeld gemonitor word. Indien jy enige veranderinge opmerk, moet jy jou dokter in kennis stel.

Ander medisyne en TRISONE NS
Stel altyd jou gesondheidswerker in kennis indien jy enige ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).
Raadpleeg jou gesondheidsorgverskaffer vir advies indien jy een van die volgende medisyne gebruik:
- Ander kortikosteroïedes wat gebruik word vir die behandeling van allergieë, hetsy per mond of per inspuiting. Jou dokter kan jou aanraai om op te hou met jou behandeling sodra jy TRISONE NS begin gebruik. 'n Klein aantal mense mag vind dat sodra hul die behandeling met hul orale kortikosteroïedes staak, dat hul ongewenste effekte kan ervaar soos gewrig- of spierpyn, swakheid en depressie. Ander allergieë kan ook ontwikkel, soos jeukerige of tranerige oë, rooi kolle op die vel of 'n jeukerige vel. Indien jy een van hierdie ongewenste effekte ontwikkel, moet jy jou dokter raadpleeg.
- Sommige medisyne kan die effekte van TRISONE NS vererger en jou dokter gaan jou noukeurig monitor indien jy die volgende medisyne gebruik (bv. medisyne wat gebruik word om MIV te behandel, soos ritonavir en kobisistaat).

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Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, of indien jy vermoed dat jy swanger is of van plan is om swanger te raak, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffers vir advies voordat jy TRISONE NS gebruik.
Jy moet nie TRISONE NS gebruik indien jy swanger is of jou baba borsvoed nie.

Bestuur en gebruik masjiene
TRISONE NS kan jou duiselig laat voel. Indien TRISONE NS jou op hierdie manier beïnvloed, moet jy nie bestuur, masjinerie gebruik of iets doen wat vereis dat jy oplettend moet wees nie.
Dit is nie altyd moontlik om te voorspel tot watter mate TRISONE NS jou daaglikse aktiwiteite kan beïnvloed nie. Jy moet toesien dat jy nie aan die bogenoemde aktiwiteite deelneem, totdat jy bewus is op watter wyse TRISONE NS jou beïnvloed nie.

TRISONE NS bevat bensalkoniumchloried
TRISONE NS bevat bensalkoniumchloried, 'n preserveermiddel wat nasale irritasie kan veroorsaak.

3. Hoe om TRISONE NS te gebruik
Moenie jou medisyne wat aan jou voorgeskryf is, met enige ander persoon deel nie.
Gebruik TRISONE NS altyd presies soos jou dokter of apteker aan jou verduidelik het. Raadpleeg jou dokter of apteker indien jy onseker is.

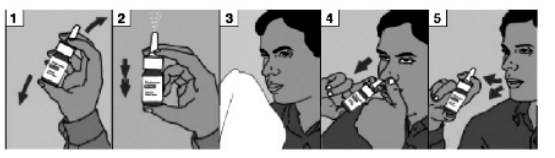
Volwassenes en tieners
Die gewone aanbevole dosis vir die voorkoming en behandeling van jou simptome is 2 spuite (50 µg/spuit) een keer per dag in elke neusgat (totale dosis 200 µg). Sodra jou simptome onder beheer is, kan jy die dosis verminder tot 1 spuit een keer per dag in elke neusgat (totale dosis 100 µg).

Indien jou simptome nie voldoende onder beheer is nie, kan jou dosis tot 'n maksimum daaglikse dosis van 4 spuite een keer per dag in elke neusgat (totale dosis 400 µg) verhoog word. Dosisvermindering word aanbeveel sodra jou simptome onder beheer is.

Kinders tussen die ouderdom van 2 en 11 jaar
Die aanbevole dosis is gewoonlik een keer per dag (50 µg/spuit) in elke neusgat (totale dosis 100 µg). Toediening aan jong kinders moet deur 'n volwassene geassisteer word.

Kinders jonger as 2 jaar
Die gebruik van TRISONE NS in kinders jonger as 2 jaar oud word nie aanbeveel nie.

Voorbereiding TRISONE NS vir gebruik:



Stap 1 en 2:
Skud die houer vóór toediening van die eerste dosis goed en voor elke gebruik. Aktiveer die spuitpomp deur ongeveer 10 keer in die lug te spuit (totdat 'n eenvormige sproei verkry is). Indien die pomp nie vir 14 dae of langer gebruik word nie, moet jy die spuitpomp weer met ongeveer 2 spuitpompe uitspuit totdat 'n eenvormige sproei waargeneem. Geen pompheraktivering is nodig na die aanvanklike aktivering indien jy TRISONE NS daagliks gebruik nie.

Stap 3:
Blaas jou neus saggies.

Stap 4:
Hou die bottel soos aangedui. Plaas jou vinger op jou neus om een neusgat toe te maak en plaas die neusspuit binne in jou ander neusgat. Kantel jou kop vorentoe en hou die bottel regop. Begin om stadig deur jou neus in te asem en druk terselfdertyd met jou vinger stewig teen die kant van die bottel, sodat dit een spuit van TRISONE NS kan vrystel.

Stap 5:
Asem uit deur jou mond. Herhaal stap 4 indien meer as een spuit in dieselfde neusgat benodig word. Haal die neusspuit uit jou neusgat en asem uit

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deur jou mond.
Herhaal stap 4 tot 5 vir die ander neusgat. Nadat jy die neussproei gebruik het, moet jy die spuitkop versigtig met ‘n skoon lap afvee en die proppie terugplaas.

Die bottel moet weggegooi word nadat die gemerkte aantal dosisse opgebruik is of binne twee maande na die eerste gebruik.

Jou dokter, apteker of verpleegster sal jou inlig hoe lank jou behandeling met TRISONE NS sal duur. Indien jy die indruk kry dat die uitwerking van TRISONE NS te sterk of te swak is, moet jy dit by jou dokter, apteker of verpleegkundige aanmeld.

Indien jy meer TRISONE NS inneem as wat jy moes
In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak jou naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om TRISONE NS in te neem
Moenie ‘n dubbele dosis gebruik om vir vergete dosisse op te maak nie.

4. Moontlike newe-effekte
TRISONE NS kan newe-effekte hê.

Nie alle newe-effekte wat vir TRISONE NS gerapporteer is, is in hierdie pamflet ingesluit nie. Raadpleeg jou gesondheidsorgverskaffer vir advies indien jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar tydens die gebruik van TRISONE NS.

Indien een van die volgende gebeur, hou dadelik op om TRISONE NS te gebruik en kontak 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 die vermoë om te sluk of asem te haal bemoeilik;
- Uitslag of jeuk;
- Floute.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit ervaar, het jy moontlik ‘n ernstige reaksie teenoor TRISONE NS gehad. Jy benodig moontlik dringende mediese hulp of hospitalisasie.

Rapporteer dit dadelik aan jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien een van die volgende opmerk:
- Toename in druk agter die oë (gloukoom) wat gesigversteurings veroorsaak;
- Skade aan die gedeelte van die neus wat die neusgate (septum) skei.

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese hulp.

Kontak jou dokter of gesondheidsorgverskaffer indien jy een van die volgende opmerk:
<u>Gereelde newe-effekte:</u>
- Inflammasie van farinks wat keelseer veroorsaak;
- Oor-, neus- en keelinfeksies;
- Hoofpyn;
- Neusbloeding;
- Brandsensasie in die neusholtes;
- Neusirritasie;
- Neusulserasie;
- Keelirritasie;
- Nies.

<u>Minder gereelde newe-effekte:</u>
- Perforasie van die neusseptum;
- Hoes;
- Loopneus;
- Smaak- en reukversteurings;
- Naarheid.

<u>Die frekwensie van newe-effekte is onbekend:</u>
- Verhoogde druk binne die oogbal, wat geleidelik verlies aan sig veroorsaak;
- Katarak, ‘n mediese toestand waarin die lens van die oog geleidelik ondeursigtig word, wat dowwe sig tot gevolg het;
- Dowwe visie;
- Inflammasie van die konjunktiva van die oog;
- Droë oë;
- Inflammasie van die slymvlies van die neus;
- Inflammasie van die sinusse;
- Duiseligheid;
- Veluitslag.

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

Rapportering van newe-effekte
Indien jy newe-effekte ervaar, moet jy jou dokter of apteker in kennis stel. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “6.04 Adverse Drug Reaction Reporting Form”, wat aanlyn onder SAHPRA se publikasies beskikbaar is:
https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy ons help om meer inligting oor die veiligheid van TRISONE NS te bekom.

5. Hoe om TRISONE NS te bewaar
Bewaar alle medisyne buite sig en bereik van kinders.
Bêre by of benede 25 ºC (kamertemperatuur).
Elke bottel moet binne twee maande na die eerste opening gebruik word.
Moenie TRISONE NS gebruik na die vervaldatum wat op die etiket of verpakking aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.
Oorhandig alle ongebruikte medisyne aan jou apteker.
Moenie ongebruikte medisyne weggooi in riool of rioolstelsels (bv. toilette) nie.

10 mm

10 mm

6. Inhoud van die verpakking en ander inligting
Wat TRISONE NS bevat
- Die aktiewe bestanddeel is mometasoonfuroaat. Elke spuit bevat 50 mikrogram mometasoonfuroaat, as monohidraat.
- Die ander bestanddele is bensalkoniumchloried, gliserol, polisorbaat 80, mikrokristallyne sellulose en natriumkarmellose, sitroensuur monohidraat, natriumsitraat en gesuiwerde water.

Hoe TRISONE NS lyk
TRISONE NS is ‘n wit tot naaswit suspensie.
TRISONE NS neussproei is verpak in ‘n wit, hoë-digtheid poliëtileenbottel, wat 10 g (60 spuite), 16 g (120 spuite) of 18 g (140 spuite) suspensie bevat en word voorsien met ‘n atomiseerpomp wat afgemete dosisse vrystel, ‘n neusstuk en ‘n proppie.
Nie alle verpakkingsgroottes word moontlik bemark nie.

Houer van Registrasiesertifikaat
Trinity Pharma (Edms.) Bpk.
16de Weg 106
Midrand
Suid-Afrika
1686

Hierdie pamflet is laas hersien in
N.A

Registrasie/Aansoeknommer
50/21.5.1/0291

Vir professionele inligting voubiljet:
www.trinitypharma.co.za

315 mm

TRINITY PHARMA

Tel: 010 594 5610. Email: PV@kahmagroup.co.za

5mm

162 mm

Black

Claudia Law - 09.05.2022