PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1 NAME OF MEDICINE
TRISONE NS
(50 micrograms (µg)/actuation, Aqueous Nasal Spray)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each metered dose pump actuation of TRISONE NS delivers mometasone furoate (as monohydrate) 50 micrograms (µg)/actuation.
TRISONE NS contains benzalkonium chloride 0,02 % m/m per actuation (as preservative).
Sugar free.
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Aqueous Nasal Spray.
White to off-white viscous suspension.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
TRISONE NS is indicated for use in adults, adolescents and children between the ages of 2 and 11 years to treat the symptoms of seasonal allergic or perennial allergic rhinitis.
In patients who have a history of moderate to severe symptoms seasonal allergic rhinitis, prophylactic treatment with TRISONE NS is recommended prior to the anticipated start of the pollen season.

4.2 Posology and method of administration
Posology
After initial priming of the TRISONE NS pump (usually 10 actuations, until a uniform spray is observed), each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 µg mometasone furoate.

Adults and adolescents
The usual recommended dose for prophylaxis and treatment is 2 sprays (50 µg/spray) into each nostril once daily (total dose 200 µg). Once symptoms are controlled, dose reduction to 1 spray into each nostril (total dose 100 µg) may be effective in some patients for maintenance.
If symptoms are inadequately controlled, the 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 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.

Paediatric populations
Safety and efficacy have not been established in children younger than 2 years old (see Section 4.3).

Method of administration
Prior to administration of the first dose, shake container well 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.
Shake container well before each use. The bottle should be discarded after the labelled number of actuations or within 2 months of first use.

4.3 Contraindications
TRISONE NS is contraindicated in:
- Patients with hypersensitivity to mometasone furoate or to any of the excipients (listed in Section 6.1);
- Pregnancy and lactation (see Section 4.6);
- Children under 2 years. Safety and efficacy have not been established (see Section 4.2).

4.4 Special warnings and precautions for use
Immunosuppression
TRISONE NS should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, or systemic viral infections.

Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Nasal inspection before and during use
Patients using TRISONE NS over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localised fungal infection of the nose or pharynx develops, discontinuance of TRISONE NS therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing TRISONE NS.
TRISONE NS should not be used in the presence of an untreated localised infection involving the nasal mucosa.
Due to the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use TRISONE NS until healing has occurred.

Septum perforation
TRISONE NS is not recommended in case of nasal septum perforation (see Section 4.8).

Epistaxis
Epistaxis may occur and is generally self-limiting and mild in severity (see Section 4.8).

Systemic effects of corticosteroids
Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Instances of increased intraocular pressure may occur following the use of intranasal corticosteroids (see Section 4.8).

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular)corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Patients who are transferred from long-term administration of systemically active corticosteroids to TRISONE NS require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency or symptoms of withdrawal (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms, systemic corticosteroid administration should be resumed, and other modes of therapy and appropriate measures instituted. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

Non-nasal symptoms
Although TRISONE NS will control the nasal symptoms in most patients, the concomitant use of appropriate additional therapy may provide additional relief of other symptoms, particularly ocular symptoms.

Paediatric population
It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist.

Excipients
TRISONE NS contains benzalkonium chloride which may cause nasal irritation.

4.5 Interaction with other medicines and other forms of interaction
Mometasone furoate has been administered concomitantly with loratadine with no apparent effect on plasma concentrations of loratadine or its major metabolite. Mometasone furoate plasma concentrations were not detectable.
Mometasone furoate is metabolised by CYP3A4.
Co-treatment with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, cobicistat-containing medicines) may lead to increased plasma concentrations of corticosteroids and potentially increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation
Safety during pregnancy and lactation has not been established (see Section 4.3).

Pregnancy
Animal studies have shown reproductive toxicity. TRISONE NS is contraindicated in pregnancy (see Section 4.3).

Lactation
It is unknown whether mometasone furoate is excreted in human milk. TRISONE NS is contraindicated during lactation (see Section 4.3).

Fertility
There are no clinical data concerning the effects of mometasone furoate on fertility. Animal studies have shown reproductive toxicity, but no effects on fertility.

4.7 Effects on ability to drive and use machines
Dizziness may occur following administration of TRISONE NS, which may affect the ability to drive and use machines (see Section 4.8).

4.8 Undesirable effects
a. Tabulated summary of adverse reactions

System Organ Class	Frequency	Undesirable effect
Infections and infestations	*Frequent*	Pharyngitis, upper respiratory infections.
	Frequency unknown	Rhinitis, sinusitis.
Immune system disorders	*Less frequent*	Hypersensitivity including allergic reactions, angioedema, bronchospasm and dyspnoea.
Nervous system disorders	*Frequent*	Headache.
Eye disorders	*Frequency unknown*	Glaucoma, increased intraocular pressure, cataracts, blurred vision, conjunctivitis, dry eyes.
Respiratory, thoracic and mediastinal disorders	*Frequent*	Epistaxis, nasal burning, nasal irritation, nasal ulceration, sneezing.
	Less frequent	Nasal septum perforation, coughing, rhinorrhoea.
Gastrointestinal disorders	*Frequent*	Throat irritation.
	Less Frequent	Taste and smell disturbances, nausea.
General disorders and administrative site disorders	*Frequency unknown*	Dizziness.
Skin and subcutaneous tissue disorders	*Frequency unknown*	Skin rash.

b. Paediatric populations
In paediatric populations, the following incidences of adverse events may occur, e.g., epistaxis, headache, nasal irritation and sneezing.
c. Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose
Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function. Systemic bioavailability of TRISONE NS is less than 0,1 %. Overdosage with TRISONE NS is therefore unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
A. 21.5.1 Corticosteroids and analogues
Pharmacotherapeutic Group: Decongestants and other nasal preparations for topical use corticosteroids
ATC Code: R01AD09
Mechanism of action
Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties.

5.2 Pharmacokinetic properties
Absorption
Mometasone furoate, administered as an aqueous nasal spray, has a systemic bioavailability of < 1 % in plasma, using a sensitive assay with a lower quantitation limit of 0,25 pg/ml.
Distribution
Mometasone furoate is poorly absorbed via the nasal route.
Biotransformation
The small amount that may be swallowed and absorbed undergoes extensive first-pass hepatic metabolism.
Elimination
Absorbed mometasone furoate is extensively metabolized and the metabolites are excreted in urine and bile.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzalkonium chloride (preservative)
Glycerol
Polysorbate 80
Dispersible cellulose (microcrystalline cellulose and carmellose sodium)
Citric acid monohydrate
Sodium citrate
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years
Use within 2 months of first use.

6.4 Special precautions for storage
Store at or below 25 ºC.

6.5 Nature and contents of container
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.
Pack sizes: 10 g (60 actuations)
16 g (120 actuations)
18 g (140 actuations)
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 HOLDERS OF CERTIFICATE OF REGISTRATION
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8 REGISTRATION NUMBER(S)
50/21.5.1/0291

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
13 July 2021

10 DATE OF REVISION OF THE TEXT
N.A

TRINITY PHARMA

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PROFESSIONELE INLIGTING

SKEDULERINGSTATUS

S2

1 NAAM VAN DIE GENEESMIDDEL
TRISONE NS
(50 mikrogram (µg)/spuit, Waterige Neussproei)

2 KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
Elke afgemete spuit wat deur die atomiseerpomp van TRISONE NS vrygestel word, lewer 50 mikrogram (µg)/spuit mometasoonfuroaat (as monohidraat).

TRISONE NS bevat bensalkoniumchloried 0,02 % m/m per afgemete spuit (as preserveermiddel).
Suikervry.

Vir 'n volledige lys van hulpstowwe, sien Afdeling 6.1.

3 FARMASEUTIESE DOSEERVORM
Waterige Neussproei.
Wit tot naaswit viskose suspensie.

4 KLINIESE BESONDERHEDE
4.1 Terapeutiese indikasies
TRISONE NS word aangedui vir die behandeling van simptome van seisoenale allergiese rinitis of aanhoudende allergiese rinitis in volwassenes, adolessente en kinders tussen die ouderdom van 2 en 11 jaar.

Voorkomende behandeling met TRISONE NS word aanbeveel voordat die stuifmeelseisoen begin in pasiënte met 'n geskiedenis van matige tot ernstige simptome van seisoenale allergiese rinitis.

4.2 Dosering en metode van toediening
Dosering
Na die aanvanklike aktivering van die TRISONE NS-spuitpomp (gewoonlik 10 spuite totdat 'n eenvormige sproei waargeneem word), lewer TRISONE NS ongeveer 100 mg mometasoonfuroaatsuspensie, wat mometasoonfuroaat monohidraat bevat wat gelykstaande is aan 50 µg mometasoonfuroaat.

Volwassenes en adolessente
Die normale aanbevole dosis vir profilakse en behandeling, is 2 spuite (50 µg/spuit) een keer per dag in elke neusgat (totale dosis is 200 µg). Sodra die simptome onder beheer is, kan die dosis verminder word tot slegs 1 spuit in elke neusgat (totale dosis 100 µg) en behoort effektief te wees om simptome te beheer.

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

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

Pediatriese populasie
Veiligheid en doeltreffendheid is nie bevestig in kinders jonger as 2 jaar oud nie (sien Afdeling 4.3).

Metode van toediening
Skud die houer goed voor gebruik en aktiveer die spuitpomp deur ongeveer 10 keer in die lug te spuit totdat 'n eenvormige sproei verkry word. Indien die neussproei nie in 14 dae of langer gebruik word nie, moet u die spuitpomp weer aktiveer deur ongeveer 2 spuite in die lug te spuit totdat u weer 'n eenvormige sproei waarneem. Geen spuitpompaktivering is nodig indien u die neussproei daagliks gebruik nie.

Skud die houer goed voor elke gebruik. Die neussproei moet weggegooi word nadat die totale aantal gemerkte dosisse opgebruik is of binne twee maande nadat u die eerste keer die neussproei begin gebruik het.

4.3 Kontra-indikasies
TRISONE NS is teenaangedui in:
- Pasiënte met hipersensitiwiteit teenoor mometasoonfuroaat of vir enige van die hulpstowwe gelys in Afdeling 6.1;
- Swangerskap en laktasie (sien Afdeling 4.6)
- Kinders jonger as 2 jaar. Veiligheid en doeltreffendheid is nie vasgestel nie (sien Afdeling 4.2).

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik
Immuunonderdrukking
TRISONE NS moet met oorsig gebruik word, indien enigsins, in pasiënte met aktiewe of latente tuberkulêre infeksies in die lugweë asook in pasiënte met onbehandelde swam-, bakteriële- of sistemiese virale infeksies.

Pasiënte met moontlike immuunonderdrukking wat kortikosteroïedes ontvang, moet gewaarsku word van die risiko ten opsigte van die blootstelling aan sekere infeksies (bv. waterpokkies, masels) en dat dit belangrik is om mediese advies in te win indien sodanige infeksies voorkom.

Neusinspeksie voor en tydens gebruik
Pasiënte wat TRISONE NS oor 'n paar maande of langer gebruik, moet gereeld ondersoek word vir moontlike veranderinge in die neusslymvliese. Indien 'n gelokaliseerde swaminfeksie in die neus of farinks ontstaan, kan dit oorweeg word om behandeling met TRISONE NS te staak of toepaslike behandeling te oorweeg. Aanhoudende nasofaringeale irritasie kan 'n aanduiding wees dat TRISONE NS-behandeling eerder gestaak moet word.
TRISONE NS moet nie gebruik word in die teenwoordigheid van 'n onbehandelde gelokaliseerde infeksie nie, wat die neusslymvliese insluit.
As gevolg van die inhiberende effek van kortikosteroïedes op wondgenesing, moet pasiënte wat onlangs 'n neusoperasie of trauma ervaar het, nie TRISONE NS gebruik, alvorens volledige genesing plaasgevind het nie.

Septumperforasie
TRISONE NS word nie aanbeveel vir gebruik in die geval van perforasie van die neusseptum nie (sien Afdeling 4.8).

Epistaksis
Epistaksis kan voorkom en is oor die algemeen selfbeperkend en nie ernstig nie (sien Afdeling 4.8).

Sistemiese effekte van kortikosteroïedes
Sistemiese effekte tydens die gebruik van nasale kortikosteroïedes kan voorkom, veral wanneer hoë dosisse vir 'n lang tydperk voorgeskryf word. Hierdie effekte kom gewoonlik baie minder voor as by die van orale kortikosteroïedes en kan wissel tussen pasiënte en verskillende kortikosteroïedpreparate. Potensiële sistemiese effekte kan die volgende insluit: Cushing-sindroom, Cushing-sindroomagtige eienskappe, onderdrukking van die bynier, groeivertraging in kinders en tieners, katarakte, gloukoom en meer selde, 'n verskeidenheid sielkundige of gedragsafwykings, insluitend psigomotoriese hiperaktiwiteit, slaapstoornisse, angs, depressie of aggressie (veral in kinders).

Gevalle van verhoogde intra-okulêre druk kan voorkom tydens die gebruik van intranasale kortikosteroïedes (sien Afdeling 4.8).

Visuele versteurings kan voorkom met die gebruik van sistemiese en topikale kortikosteroïedes (insluitend intranasale-, inhalasie- en intra-okulêre preparate). Indien 'n pasiënt simptome soos dowwe visie of ander gesigstoornisse ervaar, moet die pasiënt na 'n oogarts verwys word om die moontlike oorsake van die gesigstoornisse te ondersoek wat versteurings soos katarakte, gloukoom of seldsame siektes soos sentrale serose chorioretinopatie (CSCR) kan insluit. Hierdie toestande moet gerapporteer word indien dit ontwikkel tydens die gebruik van sistemiese en topikale kortikosteroïedes.

Pasiënte moet deurlopend gemonitor word indien hul behandeling verander word vanaf langdurige toediening van sistemies kortikosteroïedes na TRISONE NS. Sistemiese ontrekking van kortikosteroïedes in hierdie pasiënte kan tot bynieronderdrukking lei wat kan strek oor 'n tydperk van 'n aantal maande voordat die HPA-asfunksie ten volle herstel het. Indien hierdie pasiënte tekens en simptome van adrenale ontoereikendheid of onttrekkingsimptome toon (bv. gewrig- en/of spierpyn, gebrek aan energie en depressie), ten spyte van die verligting van neussimptome, moet die toediening van sistemiese kortikosteroïedes hervat word en ander behandelingsmetodes en gepaste maatreëls ingestel word. Sodanige verandering in behandeling kan ook bestaande allergiese toestande, soos allergiese konjunktivitis en ekseem, voorheen onderdruk deur sistemiese kortikosteroïedterapie, ontmasker.

Behandeling met 'n hoër as die aanbevole dosis van TRISONE NS kan lei tot klinies-beduidende onderdrukking van die bynier. Indien daar die nodige bewyse is dat 'n hoër dosis noodsaaklik is, moet addisionele sistemiese kortikosteroïedbehandeling oorweeg word gedurende periodes van spanning of elektiewe chirurgiese prosedures.

Nie-nasale simptome
Alhoewel TRISONE NS nasale simptome in meeste pasiënte beheer, kan die gepaardgaande gebruik van toepaslike addisionele terapie, verligting van ander simptome bied, veral oogsimptome.

Pediatriese populasie
Dit word aanbeveel dat die lengte van kinders gereeld gemonitor word tydens langdurige gebruik van nasale kortikosteroïedes. Indien groei vertraag word, moet die terapie hersien word met die doel om die dosis van die nasale kortikosteroïed te verminder, indien moontlik, tot die laagste dosis waarop simptome effektief beheer kan word. Daarbenewens moet die pasiënt na 'n pediatriese spesialis verwys word.

Hulpstowwe
TRISONE NS bevat bensalkoniumchloried wat nasale irritasie kan veroorsaak.

4.5 Interaksie met ander medisyne en ander vorme van interaksies
Mometasoonfuroaat is gelyktydig saam met loratadien toegedien in 'n studie om plasmakonsentrasies van loratadien en sy belangrikste metaboliete te bestudeer. Plasmakonsentrasies van mometasoonfuroaat was egter nie waarneembaar nie.

Mometasoonfuroaat word deur CYP3A4 gemetaboliseer.

Gelyktydige behandeling met sterk CYP3A-remmers (bv. ketokonasool, itrakonasool, klaritromisien, ritonavir, medisyne wat kobisistaat bevat) kan lei tot verhoogde plasmakonsentrasies van kortikosteroïedes en kan die risiko van sistemiese newe-effekte verhoog. Hierdie kombinasies moet vermy word, tensy die voordeel teenoor die verhoogde risiko van sistemiese newe-effekte regverdig. In welke geval moet pasiënte gereeld gemonitor word vir sistemiese newe-effekte van kortikosteroïedes.

4.6 Vrugbaarheid, swangerskap en laktasie
Veiligheid gedurende swangerskap en laktasie is nog nie vasgestel nie (sien Afdeling 4.3).

Swangerskap
Dierestudies het reproduksietoksisiteit getoon. TRISONE NS is teenaangedui gedurende swangerskap (sien Afdeling 4.3).

Laktasie
Dit is onbekend of mometasoonfuroaat in menslike borsmelk uitgeskei word. TRISONE NS is teenaangedui tydens borsvoeding (sien Afdeling 4.3).

Vrugbaarheid
Daar is geen kliniese data rakende die effekte van mometasoonfuroaat op vrugbaarheid nie. Dierestudies het reproduksietoksisiteit getoon, maar geen effek op vrugbaarheid nie.

4.7 Effekte op die vermoë om te bestuur en masjiene te gebruik
Duiseligheid kan voorkom na die toediening van TRISONE NS, wat die vermoë om te bestuur en masjiene te gebruik kan beïnvloed (sien Afdeling 4.8).

4.8 Ongewenste effekte
a. Opsomming van newe-effekte in tabelvorm

Orgaanklasstelsel	Frekwensie	Ongewenste effek
Infeksies en besmettings	*Gereeld*	Faringitis, infeksies in die boonste lugweë.
	Frekwensie onbekend	Rinitis, sinusitis.
Immuunstelselafwykings	*Minder gereeld*	Hipersensitiwiteit insluitend allergiese reaksies, angio-edeem, brongospasma en dispnee.
Senuweestelselafwykings	*Gereeld*	Hoofpyn.
Oogafwykings	*Frekwensie onbekend*	Gloukoom, verhoogde intra-okulêre druk, katarakte, dowwe sig, konjunktivitis, droë oë.
Asemhalings-, borskas- en mediastinumafwykings	*Gereeld*	Epistaksis, brandgevoel in nasale weë, nasale irritasie, nasale ulserasie, nies.
	Minder gereeld	Nasale septumperforasie, hoes, rinorree.
Gastro-intestinale afwykings	*Gereeld*	Keelirritasie.
	Minder gereeld	Smaak en reukversteurings, naarheid.
Algemene afwykings en area van toediening afwykings	*Frekwensie onbekend*	Duiseligheid.
Vel- en subkutaneuse weefselafwykings	*Frekwensie onbekend*	Veluitslag.

b. Pediatriese populasies
In pediatriese populasies kan die volgende newe-effekte voorkom, byvoorbeeld epistaksis, hoofpyn, neusirritasie en nies.
c. Aanmelding van vermeende newe-reaksies
Die aanmelding van vermoedelike newe-reaksies na goedkeuring van hierdie medisyne is belangrik. Dit laat voortgesette monitering ten opsigte van die voordeel/risikobalans van die medisyne toe. Gesondheidsorgverskaffers word gevra om enige vermeende newe-reaksies aan SAHPRA te rapporteer via die "**6.04 Adverse Drug Reactions Reporting Form**", wat aanlyn onder SAHPRA se publikasies voorkom: https://www.sahpra.org.za/Publications/Index/8

4.9 Oordosering
Inaseming of toediening van buitensporige orale dosisse van kortikosteroïedes kan lei tot die onderdrukking van die HPA-asfunksie. Sistemiese biobeskikbaarheid van TRISONE NS is minder as 0,1 %. Dit is dus hoogs onwaarskynlik dat oordosering met TRISONE NS enige ander behandeling behalwe monitering benodig, gevolg deur die aanvang van die korrekte dosis.

5 FARMAKOLOGIESE EIENSKAPPE
5.1 Farmakodinamiese eienskappe
A. 21.5.1 Kortikosteroïede en analoë
Farmakoterapeutiese Groep: Dekongestante en ander nasale preparate vir topikale gebruik van kortikosteroïedes
ATC Kode: R01AD09

Werkingsmeganisme
Mometasoonfuroaat is 'n topikale glukokortikosteroïed met plaaslike anti-inflammatoriese eienskappe.

5.2 Farmakokinetiese eienskappe
Absorpsie
Mometasoonfuroaat, toegedien as 'n waterige neussproei, toon met behulp van 'n analitiese toets (met 'n onderste kwantifiseringslimiet van 0,25 pg/ml), 'n sistemiese biobeskikbaarheid van <1 % in plasma.

Verspreiding
Mometasoonfuroaat word swak deur die neus geabsorbeer.

Biotransformasie
Die klein hoeveelheid geneesmiddel wat moontlik ingesluk en geabsorbeer kan word, ondergaan ekstensiewe metabolisme deur middel van die eerste deurgangseffek.

Uitskeiding
Geabsorbeerde mometasoonfuroaat word ekstensief gemetaboliseer en die metaboliete word deur middel van die urine en gal uitgeskei.

6 FARMASEUTIESE BESONDERHEDE
6.1 Lys van hulpstowwe
Bensalkoniumchloried (preserveermiddel)
Gliserol
Polisorbaat 80
Dispergeerbare sellulose (mikrokristallyne sellulose en natriumkarmellose)
Sitroensuur monohidraat
Natriumsitraat
Gesuiwerde water

6.2 Onversoenbaarheid
Nie van toepassing nie.

6.3 Rakleeftyd
2 jaar
Gebruik binne 2 maande na eerste gebruik.

6.4 Spesiale voorsorgmaatreëls
Bewaar by of benede 25 ºC.

6.5 Aard en inhoud van die houer
TRISONE NS suspensie word verpak in 'n wit, hoë-digtheid poliëtileenbottel, wat 10 g (60 spuite), 16 g (120 spuite) of 18 g (140 spuite) bevat en word voorsien met 'n atomiseerpomp wat afgemete dosisse vrystel, 'n neusstuk en 'n prop.
Verpakkingsgroottes: 10 g (60 spuite)
16 g (120 spuite)
18 g (140 spuite)
Nie alle verpakkingsgroottes word moontlik bemark nie.

6.6 Spesiale voorsorgmaatreëls vir wegdoening en ander hantering
Ongebruikte medisyne of afvalsmateriaal moet in ooreenstemming met plaaslike vereistes weggegooi word.

7 HOUER VAN REGISTRASIESERTIFIKAAT
Trinity Pharma (Edms.) Bpk.
16de Weg 106
Midrand
Suid-Afrika
1686

8 REGISTRASIENOMMER(S)
50/21.5.1/0291

9 DATUM VAN EERSTE MAGTIGING / HERNUWING VAN DIE MAGTIGING
13 Julie 2021

10 DATUM VAN HERSIENING VAN DIE TEKS
N.V.T