Patient information leaflet

Scheduling status
Schedule 0

Proprietary name, strength and pharmaceutical form

Euphorbium
compositum® Nasal Spray S

Read all of this leaflet carefully because it contains important information for you.
Euphorbium compositum® Nasal Spray S is available without a doctor's prescription, for you to treat a mild illness.
Nevertheless you still need to use Euphorbium compositum® Nasal Spray S carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Euphorbium compositum® Nasal Spray S with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. What Euphorbium compositum® Nasal Spray S contains

1 ml cont.:
The active substances are: Euphorbium D4 0,01 ml; Pulsatilla pratensis D2 0,01 ml; Luffa operculata D2 0,01 ml; Mercurius bijodatus D8 0,01 ml; Mucosa nasalis suis D8 0,01 ml; Hepar sulfuris D10 0,01 ml; Argentum nitricum D10 0,01 ml; Sinusitis-Nosode D13 0,01 ml.
The other ingredients are: water, purified; disodium phosphate dehydrate; sodium chloride; sodium dihydrogen phosphate dehydrate.
Preservative: benzalkonium chloride 0,01 %.

2. What Euphorbium compositum® Nasal Spray S is used for

Pharmacological classification: D. 33.2. Homeopathy.
Discipline of the medicine: Homeopathy.

This medicine is prepared in accordance with homeopathic principles and is proposed for use in rhinitis of varied origins (viral, bacterial, allergic); rhinitis sicca, rhinitis hyperplastica and atrophicans, for the auxiliary treatment of ozena; chronic sinusitis; to facilitate nasal respiration in hay fever.

3. Before you use Euphorbium compositum® Nasal Spray S

Do not use Euphorbium compositum® Nasal Spray S:
- if you are hypersensitive (allergic) to active substances or any of the other ingredients of Euphorbium compositum® Nasal Spray S.
- if you are hypersensitive to benzalkonium chloride.

Warnings
This medicinal product contains 0,012 mg benzalkonium chloride in each spray which is equivalent to 1 mg / 10 g. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Taking other medicines with Euphorbium compositum® Nasal Spray S:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Euphorbium compositum® Nasal Spray S with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. How to use Euphorbium compositum® Nasal Spray S

Do not share medicines prescribed for you with any other person. Always use Euphorbium compositum® Nasal Spray S exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is:
Adults: 1-2 sprays into each nostril 3-5 times daily.
Children 2-5 years: 1 spray into each nostril 3-4 times daily.

Do not administer to children younger than 2 years.

Instructions for the correct use of the preparation (see back of page).

If you use more Euphorbium compositum® Nasal Spray S than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you missed a dose of Euphorbium compositum® Nasal Spray S:
Do not take a double dose to make up for forgotten individual doses.

5. Possible side effects

Euphorbium compositum® Nasal Spray S can have side effects.
Irritation of the nasal mucosae with burning and increased nasal secretion may occur in very rare cases after use of Euphorbium compositum® Nasal Spray S, in which case the use of the product should be discontinued. In very rare cases, bronchospasm may occur in predisposed asthmatic patients. Not all side effects reported for Euphorbium compositum® Nasal Spray S are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. Storing and disposing of Euphorbium compositum® Nasal Spray S

Keep all medicines out of the reach and sight of children.
- Store in a cool (below 25 °C) place.
- Replace cap tightly.

7. Presentation of Euphorbium compositum® Nasal Spray S

Atomiser without propellant, 20 ml.

8. Identification of Euphorbium compositum® Nasal Spray S

Clear to light yellow solution.

9. Registration number / Reference number

U 5584 (Act 101/1965)

10. Name and business address of the holder of the certificate of registration

ModHomCo (Pty) Ltd
96 Amsterdam Street, Clubview, 0157 Centurion

11. Date of publication

January 2024

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Pasiënt-inligtingstuk 015191/5011/ZA

Skeduleringstatus
Skedule 0

Handelsnaam, sterkte en farmaseutiese vorm

Euphorbium
compositum® Neussproei S

Lees die volledige inligtingstuk noukeurig aangesien dit belangrike inligting bevat.
Euphorbium compositum® Neussproei S is sonder 'n doktersvoorskrif aan u beskikbaar om 'n ligte siekte mee te behandel.
Nogtans moet u Euphorbium compositum® Neussproei S versigtig gebruik om die beste resultate te verkry.
- Hou hierdie inligtingstuk. U mag dit weer moet lees.
- Moenie Euphorbium compositum® Neussproei S met enige ander persoon deel nie.
- Vra u apteker indien u meer inligting of advies benodig.
- U moet 'n geneesheer raadpleeg indien u simptome vererger of nie verbeter nie.

1. Wat Euphorbium compositum® Neussproei S bevat

1 ml bevat.:
Die aktiewe bestanddele is: Euphorbium D4 0,01 ml; Pulsatilla pratensis D2 0,01 ml; Luffa operculata D2 0,01 ml; Mercurius bijodatus D8 0,01 ml; Mucosa nasalis suis D8 0,01 ml; Hepar sulfuris D10 0,01 ml; Argentum nitricum D10 0,01 ml; Sinusitis-Nosode D13 0,01 ml.
Die ander bestanddele is: gesuiwerde water; dinatriumfosfaat-dehidraat; natriumchloried; natrium-dihidrogeenfosfaat dehidraat.
Preserveermiddel: benzalkoniumchloried 0,01 %.

2. Waarvoor Euphorbium compositum® Neussproei S gebruik word

Farmakologiese klassifikasie: D. 33.2. Homeopatie.
Dissipline van die medisyne: Homeopatie.

Hierdie medisyne is in ooreenstemming met homeopatiese beginsels voorberei en word voorgestel vir gebruik in rhinitis van verskeie oorspronge (viraal, bakteriëel, allergies); rhinitis sicca, rhinitis hyperplastica en atrophicans, vir die aanvullende behandeling van ozena; chroniese sinusitis; om nasale respirasie in hooikoors te fasiliteer.

3. Voordat u Euphorbium compositum® Neussproei S gebruik

Moenie Euphorbium compositum® Neussproei S gebruik:
- indien u hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van Euphorbium compositum® Neussproei S.
- indien u hipersensitief is vir benzalkoniumchloried.

Waarskuwings
Hierdie medisinale produk bevat 0,012 mg benzalkoniumchloried in elke sproei wat ekwivalent is aan 1 mg/10 g. Benzalkoniumchloried mag irritasie of swelling binne die neus veroorsaak, veral as dit vir 'n lang tydperk gebruik word.

Swangerskap en borsvoeding
Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne gebruik, raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

Die neem van ander medisyne met Euphorbium compositum® Neussproei S:
Indien u enige ander medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van Euphorbium compositum® Neussproei S met hierdie medisyne ongewenste interaksies tot gevolg hê. Raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

4. Hoe om Euphorbium compositum® Neussproei S te gebruik

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Gebruik Euphorbium compositum® Neussproei S presies soos u geneesheer dit voorgeskryf het. U moet u geneesheer op apteker raadpleeg indien u onseker is.
Die gewone dosis is:
Volwassenes: 1-2 sproeie in elke neusgang 3-5 maal per dag.
Kinders 2-5 jaar: 1 sproei in elke neusgang 3-4 maal per dag.

Moenie aan kinders onder die ouderdom van 2 jaar toedien nie.

Instruksies vir die korrekte gebruik van hierdie preparaat (sien keersy).

Indien u meer Euphorbium compositum® Neussproei S gebruik as wat u moet:
In die geval van 'n oordosering, raadpleeg u geneesheer of apteker. Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.

Indien u 'n dosis van Euphorbium compositum® Neussproei S nie gebruik het nie:
Moenie 'n dubbeldosis gebruik om op te maak vir 'n vergete individuele dosis nie.

5. Moontlike newe-effekte

Euphorbium compositum® Neussproei S kan newe-effekte hê.
Irritasie van die neusslymvliese met 'n brandgevoel en verhoogde nasale sekresie mag in baie seldsame gevalle na die gebruik van Euphorbium compositum® Neussproei S voorkom, in welke geval die gebruik van die produk gestaak moet word. In baie seldsame gevalle mag bronchospasma in vatbare asmatiese pasiënte voorkom. Nie alle newe-effekte wat vir Euphorbium compositum® Neussproei S gerapporteer is, word in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheid vererger terwyl u hierdie medisyne gebruik, raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies. Indien u enige newe-effekte ervaar wat nie in hierdie inligtingstuk ingesluit is nie, lig asseblief u geneesheer of apteker daarvan in.

6. Opberging van en beskikking oor Euphorbium compositum® Neussproei S

Hou alle medisyne buite die bereik en sig van kinders.
- Hou in 'n koel (onder 25 °C) plek.
- Plaas proppie styf terug.

7. Aanbieding van Euphorbium compositum® Neussproei S

Sproeibottel sonder aandrywer, 20 ml.

8. Identifikasie van Euphorbium compositum® Neussproei S

Helder tot liggeel oplossing.

9. Registrasienommer / Verwysingsnommer

U 5584 (Wet 101/1965)

10. Naam en besigheidsadres van die houer van die registrasiesertifikaat

ModHomCo (Edms) Bpk
Amsterdamstraat 96, Clubview, 0157 Centurion

11. Datum van publikasie

Januarie 2024

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA vir kwaliteit, veiligheid of beoogde gebruik geëvalueer nie.

-Heel

Professional Information

Euphorbium
compositum® Nasal Spray S

1. Scheduling status

Schedule 0

2. Proprietary name and dosage form

Euphorbium compositum® Nasal Spray S
Nasal spray

3. Composition

1 ml cont.:
The active substances are: Euphorbium D4 0,01 ml; Pulsatilla pratensis D2 0,01 ml; Luffa operculata D2 0,01 ml; Mercurius bijodatus D8 0,01 ml; Mucosa nasalis suis D8 0,01 ml; Hepar sulfuris D10 0,01 ml; Argentum nitricum D10 0,01 ml; Sinusitis-Nosode D13 0,01 ml.
The other ingredients are: water, purified; disodium phosphate dehydrate; sodium chloride; sodium dihydrogen phosphate dehydrate.
Preservative: benzalkonium chloride 0,01 %.

4. Pharmacological classification

D. 33.2. Homeopathy.

5. Pharmacological action

Action based on homeopathic principles.

6. Indications

This medicine is prepared in accordance with homeopathic principles and is proposed for use in rhinitis of varied origins (viral, bacterial, allergic); rhinitis sicca, rhinitis hyperplastica and atrophicans, for the auxiliary treatment of ozena; chronic sinusitis; to facilitate nasal respiration in hay fever.

7. Contraindications

Hypersensitivity to any of the ingredients, including excipients.
Hypersensitivity to benzalkonium chloride.

8. Warnings

If symptoms persist or worsen you should consult a healthcare professional. This medicinal product contains 0,012 mg benzalkonium chloride in each spray which is equivalent to 1 mg / 10 g. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

9. Interactions

No interactions studies have been performed.

10. Pregnancy and lactation

Safety and/or efficacy has not been established.

11. Dosage and directions for use

Adults: 1-2 sprays into each nostril 3-5 times daily.
Children 2-5 years: 1 spray into each nostril 3-4 times daily.

Do not administer to children younger than 2 years.

12. Side effects and special precautions

12.1 Side effects

Irritation of the nasal mucosae with burning and increased nasal secretion may occur in very rare cases after use of Euphorbium compositum® Nasal Spray S, in which case the use of the product should be discontinued. In very rare cases, bronchospasm may occur in predisposed asthmatic patients.

12.2 Special precautions

12.3 Effects on ability to drive and use machines

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13. Known symptoms of overdosage and particulars of its treatment

None known.

14. Identification

Clear to light yellow solution.

15. Presentation

Atomiser without propellant, 20 ml.

16. Storage instructions

Store in a cool (below 25 °C) place beyond the reach of children.
Replace cap tightly.

17. Registration number

U 5584 (Act 101/1965)

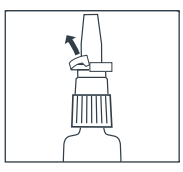
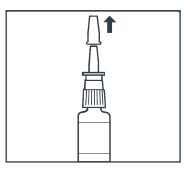
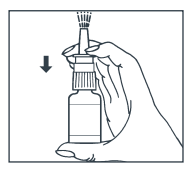
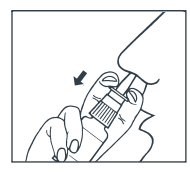
18. Name and business address of the holder of the certificate of registration

ModHomCo (Pty) Ltd
96 Amsterdam Street
Clubview, 0157 Centurion
Manufactured in Germany.

19. Date of publication

January 2024

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Instructions for the correct use of the preparation.
Ensure that the tamper proof seal is intact before using for the first time.
Do not use if this seal is broken.
1. Remove the cap.
2. Pump microdoser several times for first application until an even spray emits.
3. Gently insert tip into nostril and spray as directed. Inhale deeply through the nose. Wipe tip clean and replace cap after each use.

Professionele Inligting

Euphorbium
compositum® Neussproei S

1. Skeduleringstatus

Skedule 0

2. Handelsnaam en doseervorm

Euphorbium compositum® Neussproei S
Neussproei

3. Samestelling

1 ml bevat.:
Die aktiewe bestanddele is: Euphorbium D4 0,01 ml; Pulsatilla pratensis D2 0,01 ml; Luffa operculata D2 0,01 ml; Mercurius bijodatus D8 0,01 ml; Mucosa nasalis suis D8 0,01 ml; Hepar sulfuris D10 0,01 ml; Argentum nitricum D10 0,01 ml; Sinusitis-Nosode D13 0,01 ml.
Die ander bestanddele is: gesuiwerde water; dinatriumfosfaat-dehidraat; natriumchloried; natrium-dihidrogeenfosfaat dehidraat.
Preserveermiddel: benzalkoniumchloried 0,01 %.

4. Farmakologiese klassifikasie

D. 33.2. Homeopatie.

5. Farmakologiese werking

Werking gebaseer op homeopatiese beginsels.

6. Indikasies

Hierdie medisyne is voorberei in ooreenstemming met homeopatiese beginsels en word voorgestel vir gebruik in rhinitis van verskeie oorsprong (viraal, bakteriëel, allergies); rhinitis sicca, rhinitis hyperplastica en atrophicans, vir die aanvullende behandeling van ozena; chroniese sinusitis; om nasale respirasie in hooikoors te fasiliteer.

7. Kontra-indikasies

Hipersensitiwiteit vir enige van die bestanddele, insluitend die bymiddels.
Hipersensitiwiteit vir benzalkoniumchloried.

8. Waarskuwings

Indien simptome voortduur of vererger, raadpleeg 'n professionele gesondheidswerker. Hierdie medisinale produk bevat 0,012 mg benzalkoniumchloried in elke sproei wat ekwivalent is aan 1 mg/10 g. Benzalkoniumchloried mag irritasie of swelling binne die neus veroorsaak, veral as dit vir 'n lang tydperk gebruik word.

9. Interaksies

Geen interaksie-studies is uitgevoer nie.

10. Swangerskap en borsvoeding

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

11. Dosering en gebruiksaanwysings

Volwassenes: 1-2 sproeie in elke neusgang 3-5 maal per dag.
Kinders 2-5 jaar: 1 sproei in elke neusgang 3-4 maal per dag.

Moenie aan kinders jonger as 2 jaar toedien nie.

12. Newe-effekte en spesiale voorsorgmaatreëls

12.1 Newe-effekte

Irritatasie van die neusslymvliese met brand en verhoogde nasale sekresie mag in baie skaars gevalle voorkom na die gebruik van Euphorbium compositum® Neussproei S, in welke geval gebruik van die produk gestaak moet word. In uiters seldsame gevalle mag bronchospasma in vatbare asmatiese pasiënte voorkom.

12.2 Spesiale voorsorgmaatreëls

12.3 Effek op die vermoë om te bestuur en om masjinerie te gebruik

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13. Bekende simptome van oordosering en besonderhede van die behandeling daarvan

Geen bekend.

14. Identifikasie

Helder tot liggeel oplossing.

15. Aanbieding

Verstuiwer sonder dryfmiddel, 20 ml.

16. Opbergingsinstruksies

Hou in 'n koel (onder 25 °C) plek buite die bereik van kinders.
Plaas proppie styf terug.

17. Registrasienommer

U 5584 (Wet 101/1965)

18. Naam en besigheidsadres van die houer van die registrasiesertifikaat

ModHomCo (Edms) Bpk
Amsterdamstraat 96
Clubview, 0157 Centurion
Vervaardig in Duitsland.

19. Datum van publikasie

Januarie 2024

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA vir kwaliteit, veiligheid of beoogde gebruik geëvalueer nie.

Instruksies vir die korrekte gebruik van hierdie preparaat.
Verseker dat die peutervrye seël ongeskonde is voor die eerste gebruik.
Moenie gebruik indien hierdie seël gebreek is nie.
1. Verwyder die doppie.
2. Pomp die mikrodoseerder verskeie keer vir die eerste toediening totdat die sproei egalig is.
3. Plaas die punt versigtig in die neusgang en sproei soos voorgeskryf. Asem diep deur die neus in. Vee die punt af en plaas die doppie terug na elke gebruik.

-Heel