PROFESSIONAL INFORMATION FOR GASGON

AYURVEDIC MEDICINE

SCHEDULING STATUS
S0

PROPRIETARY NAME AND DOSAGE FORM
GASGON soft gelatin capsule

COMPOSITION
Active ingredients:
Each soft gelatin capsule contains:

Ajowan oil	10 mg
Caraway oil	10 mg
Cardamom oil	10 mg
Coriander oil	10 mg
Fennel oil	10 mg
Menthol	5 mg

Inactive ingredients:
Gelatin, glycerine, methyl paraben sodium, propyl paraben sodium, purifiied water, sorbitol, sunflower oil, vitamin E acetate.
Contains sugar.

CATEGORY AND CLASS
D33.8 Other Herbal
Complementary Medicine: Ayurvedic Medicine

PHARMACOLOGICAL ACTION
Ajowan oil is extracted from *Trachyspermum ammi* or commonly known as Bishop's weed. It is a common spice in India and is traditionally used as an anti-flatulent.

Caraway oil is extracted from *Carum carvi* or commonly known as meridian fennel or Persian cumin. Caraway fruits contain 2 to 7 % volatile oil, consisting of mainly carvone and limonene. In combination with peppermint oil (menthol) caraway oil may reduce gastroduodenal motility.

Cardamom oil is extracted from *Elettaria cardamomum* and is commonly known as cardamom. Cardamom seeds contain volatile oils including cineole. Cardamom oil is traditionally used for its antispasmodic and anti-flatulent properties.

Coriander oil is extracted from *Coriandrum sativum* and is also known as cilantro. Coriander is a source of vitamin C, calcium, magnesium, potassium and iron. Coriander is traditionally used to alleviate abdominal pain and discomfort in patients with irritable bowel syndrome.

Fennel oil is extracted from *Foeniculum vulgare*. Fennel seeds contain volatile oils including trans-anethole. Fennel is traditionally used to alleviate digestive related symptoms, including bloating and flatulence.

Menthol is an organic compound obtained from peppermint or other mint oils. It has many traditional uses including flatulence, cramps and dyspepsia.

INDICATIONS
GASGON is used for the temporary relief of gas related problems in the stomach and digestive tract, such as flatulence, bloating and belching.

CONTRAINDICATIONS
Hypersensitivity to ajowan oil, caraway oil, cardamom oil, coriander oil, fennel oil, menthol or to any of the inactive ingredients of **GASGON** (see **COMPOSITION**).

WARNINGS and SPECIAL PRECAUTIONS
Menthol
The use of menthol is not recommended in patients with known history of seizures.

Ajowan
Caution is advised in patients with hepatic impairment. Ajowan may slow blood clotting and increase the risk of bleeding during surgery. Patients should be advised to stop using **GASGON** at least two weeks prior to scheduled surgery.

Caraway
Caution is advised in patients with diabetes, since caraway may cause a lowering in blood sugar. A dosage adjustment of medicines used to treat diabetes may be required, if used concomitantly with **GASGON**. Patients with diabetes should be advised to stop using **GASGON** at least two weeks prior to scheduled surgery.

Cardamom
Caution is advised in patients with gallstones. **GASGON** may aggravate spasmodic pain in these patients.

Effects on ability to drive and use machines:
GASGON may impair the ability to drive a vehicle or operate machinery. Affected patients should not drive a vehicle or operate machinery.

INTERACTIONS
Fennel
Fennel, as in **GASGON**, may interact with oral contraceptives, ciprofloxacin, oestrogen and tamoxifen.

Menthol
Menthol may interact with medicines acting on the cytochrome P450 1A2 (CYP1A2) substrates, such as amitriptyline, haloperidol, ondansetron, propranolol, theophylline and verapamil.
Menthol may interact with medicines acting on the cytochrome P450 2C19 (CYP2C19) substrates such as omeprazole, lansoprazole, pantoprazole, diazepam, carisoprodol and nelfinavir.
Menthol may interact with medicines acting on the cytochrome P450 2C9 (CYP2C9) substrates such as diclofenac, ibuprofen, meloxicam, piroxicam, celecoxib, amitriptyline, warfarin, glipizide and losartan.
Menthol may interact with medicines acting on the cytochrome P450 3A4 (CYP3A4) substrates such as lovastatin, ketoconazole, itraconazole, fexofenadine and triazolam.

HUMAN REPRODUCTION
Safety during pregnancy and lactation has not been established. **GASGON** should not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE
Adults and children over 12 years:
Take one capsule twice daily after a meal, or as recommended by your doctor.

Do not exceed the maximum daily dose of two capsules.

SIDE EFFECTS
Immune system disorders:
Frequency unknown: Hypersensitivity reactions.

Nervous system disorders:
Frequency unknown: Headache.

Gastrointestinal disorders:
Frequency unknown: Dyspepsia, mouth ulcers, gastric discomfort or pain.

Skin and subcutaneous tissue disorders:
Frequency unknown: Skin rash.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Treatment should be symptomatic and supportive.

IDENTIFICATION
Golden colour, oval shaped, soft gelatin capsule containing a colourless liquid.

PRESENTATION
Clear PVDC / aluminium blister strips of 10 capsules.
Pack size: 30 capsules packed into an outer carton.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Keep in outer carton until required for use.
Protect from heat and light.
KEEP OUT OF REACH OF CHILDREN.

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

REGISTRATION NUMBER
To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Lamar International (Pty) Ltd
13 Pasita Street
Rosen Heights, Rosen Park
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September 2018

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PROFESSIONELE INLIGTING VIR GASGON

AYURVEDIESE MEDISYNE

SKEDULERINGSTATUS
S0

EIENDOMSNAAM EN DOSEERVORM
GASGON sagte gelatien kapsule

SAMESTELLING
Aktiewe bestanddele:
Elke sagte gelatien kapsule bevat:

Ajowanolie	10 mg
Karwyolie	10 mg
Kardemomolie	10 mg
Koljanderolie	10 mg
Vinkelolie	10 mg
Mentol	5 mg

Onaktiewe bestanddele:
Gelatien, gliserien, natriummetielparabeen, natriumpropielparabeen, gesuiwerde water, sorbitol, sonneblomolie, vitamien E-asetaat.
Bevat suiker.

KATEGORIE EN KLAS
D33.8 Ander Kruiemedisyne
Komplementêre Medisyne: Ayurvediese Medisyne

FARMAKOLOGIESE WERKING
Ajowanolie word uit *Trachyspermum ammi*, algemeen bekend as kantblom, geëkstraheer. Dit is 'n gewilde spesery in Indië en word tradisioneel as antiflatulent (middel teen winderigheid) gebruik.

Karwyolie word geëkstraheer uit *Carum carvi* en is algemeen bekend as meridiaan-vinkel of Persiese komyn. Karwyvruggies bevat 2 tot 7 % vlugtige olies, wat hoofsaaklik uit karvoon en limoneen bestaan. In kombinasie met pepermentolie (mentol) mag karwyolie gastroduodenale motiliteit verminder.

Kardemomolie word geëkstraheer uit *Elettaria cardamomum* en dis algemeen bekend as kardemom. Kardemomsade bevat vlugtige olies, insluitende sineool. Kardemomolie word tradisioneel gebruik vir die antispasmodiese en antiflatulente eienskappe daarvan.

Koljanderolie word geëkstraheer uit *Coriandrum sativum* en is ook bekend as silantro of Chinese pietersielie. Koljander is 'n bron van vitamien C, kalsium, magnesium, kalium en yster. Koljander word tradisioneel gebruik om buikpyn en -ongemak te verlig in pasiënte met prikkelbare dermsindroom.

Vinkelolie word geëkstraheer uit *Foeniculum vulgare*. Vinkelsade bevat vlugtige olies, insluitend trans-anetool. Vinkel word tradisioneel gebruik om spysverteringsverwante simptome te verlig, insluitend opgeblasenheid en flatulensie (winderigheid).

Mentol is 'n organiese verbinding wat verkry word uit peperment- of ander mentolies. Dit het baie tradisionele gebruike, insluitend vir flatulensie, krampe en dispepsie.

INDIKASIES
GASGON word gebruik vir die tydelike verligting van gasverwante probleme in die maag en spysverteringskanaal, soos flatulensie (winderigheid), opgeblasenheid en windopbreking.

KONTRA-INDIKASIES
Hipersensitiwiteit vir ajowanolie, karwyolie, kardemomolie, koljanderolie, vinkelolie, mentol of vir enige van die onaktiewe bestanddele van **GASGON** (kyk **SAMESTELLING**).

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS
Mentol
Die gebruik van mentol word nie aanbeveel by pasiënte wat 'n geskiedenis van toevalle (stuiptrekkings) het nie.

Ajowan
Versigtigheid word aanbeveel by pasiënte met belemmerde lewerfunksie. Ajowan mag bloedstolling vertraag en die risiko van bloeding tydens chirurgie verhoog. Pasiënte moet aangeraai word om ten minste twee weke voor die beplande chirurgie op te hou om **GASGON** te gebruik.

Karwy
Versigtigheid word aanbeveel by pasiënte met diabetes, aangesien karwy bloedsuiker kan verlaag. Dit mag nodig wees om die dosering van medisyne wat gebruik word om diabetes te behandel aan te pas, indien dit saam met **GASGON** gebruik word. Pasiënte met diabetes moet aangeraai word om ten minste twee weke voor beplande chirurgie op te hou om **GASGON** te gebruik.

Kardamom
Versigtigheid word aanbeveel by pasiënte met galstene. **GASGON** mag die spasmodiese pyn by hierdie pasiënte vererger.

Uitwerking op die vermoë om 'n voertuig te bestuur en masjinerie te hanteer:
GASGON mag die vermoë om 'n voertuig te bestuur of masjinerie te hanteer, belemmer.
Aangetaste pasiënte moenie 'n voertuig bestuur of masjinerie hanteer nie.

INTERAKSIES
Vinkel
Vinkel, soos in **GASGON**, mag wisselwerking hê met mondelingse voorbehoedmiddels, siprofloksasien, estrogeen en tamoksifeen.

Mentol
Mentol mag wisselwerking hê met medisynes wat inwerk op die sitochroom P450 1A2 (CYP1A2) substrate, soos amitriptilien, haloperidol, ondansetron, propranolol, teofillien en verapamiel.

Mentol mag wisselwerking hê met medisynes wat inwerk op die sitochroom P450 2C19 (CYP2C19) substrate, soos omeprasool, lansoprasool, pantoprasool, diasepaam, karisoprodol en nelfinavir.

Mentol mag wisselwerking hê met medisynes wat inwerk op die sitochroom P450 2C9 (CYP2C9) substrate, soos diklofenak, ibuprofeen, meloksikaam, piroksikaam, selekoksib, amitriptilien, warfarien, glipisied en losartaan.

Mentol mag wisselwerking hê met medisynes wat inwerk op die sitochroom P450 3A4 (CYP3A4) substrate, soos lovastatien, ketokonasool, itrakonasool, feksofenadien en triasolaam.

MENSLIKE VOORTPLANTING
Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. **GASGON** moet nie tydens swangerskap en borsvoeding gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes en kinders ouer as 12 jaar:
Neem een kapsule twee keer per dag na 'n maaltyd, of soos deur u dokter aanbeveel.

Moenie die maksimum daaglikse dosis van twee kapsules oorskry nie.

NEWE-EFFEKTE
Immuunstelselversteurings:
Frekwensie onbekend: Hipersensitiwiteitsreaksies.

Senuweestelselversteurings:
Frekwensie onbekend: Hoofpyn.

Gastro-intestinale versteurings:
Frekwensie onbekend: Dispepsie, mondulkusse, gastriese ongemak of pyn.

Vel- en subkutaneweefselversteurings:
Frekwensie onbekend: Veluitslag.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Behandeling moet simptomaties en ondersteunend wees.

IDENTIFIKASIE
Goudkleurige, ovaalvormige, sagte gelatien kapsule wat 'n kleurlose vloeistof bevat.

AANBIEDING
Helder PVDC / aluminiumstulpstroke met 10 kapsules.
Verpakkingsgrootte: 30 kapsules word in 'n buitenste karton verpak.

BERGINGSINSTRUKSIES
Bewaar by of benede 25 °C.
Hou stulpstroke in die buitenste karton tot nodig vir gebruik.
Beskerm teen hitte en lig.
HOU BUITE BEREIK VAN KINDERS.

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

REGISTRASIENOMMER
Sal toegeken word.

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