

SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

GAVISCON LIQUID ANISEED Suspension

Sodium alginate 500 mg and Sodium bicarbonate 267 mg per 10 ml

Read this entire leaflet carefully because it contains important information for you.

This medicine is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use GAVISCON LIQUID ANISEED carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice.
- Do not share Gaviscon Liquid Aniseed with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

1. WHAT GAVISCON LIQUID ANISEED CONTAINS:

Each 10 ml of GAVISCON LIQUID ANISEED contains sodium alginate 500 mg and Sodium Bicarbonate 267 mg.

The other ingredients are calcium carbonate carbomer, sodium saccharin, fennel flavour, erythrosine, sodium hydroxide and water.

Preservatives: Methylhydroxybenzoate 0,4% m/v and Propylhydroxybenzoate 0,06% m/v.

Contains sweetener (Saccharin sodium 0,100% m/v).

2. WHAT GAVISCON LIQUID ANISEED IS USED FOR:

GAVISCON LIQUID ANISEED is used for the following conditions: gastric reflux (reflux of stomach contents into the oesophagus); reflux oesophagitis (inflamed foodpipe); heartburn, including heartburn during pregnancy; and conditions associated with gastric reflux including hiatus hernia (protrusion of muscle through a muscle wall); flatulence (accumulation of gas in the stomach or intestines); epigastric and retrosternal distress.

3. BEFORE YOU TAKE GAVISCON LIQUID ANISEED

Do not take GAVISCON LIQUID ANISEED:

- If you are hypersensitive (allergic) to sodium alginate or any other ingredients.

Contains methyl parahydroxybenzoate and propyl parahydroxybenzoate: May cause allergic reactions (possibly delayed)

Take special care with GAVISCON LIQUID ANISEED:

- If you have heart disease or high blood pressure
- If you are receiving corticosteroids
- If you have kidney disease, electrolyte imbalances (e.g. low calcium levels) or cirrhosis of the liver.
- Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis, and recurrent calcium containing renal calculi.

Taking GAVISCON LIQUID ANISEED with food and drink:

This medicine is usually taken after meals and at bedtime.

Pregnancy and breast-feeding:

GAVISCON LIQUID ANISEED is used for heartburn of pregnancy.

No effects of GAVISCON LIQUID ANISEED have been shown in breast fed newborns/infants of treated mothers. Gaviscon can be used during breastfeeding.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional of advice.

Fertility:

GAVISCON LIQUID ANISEED has no negative effect in parental or offspring fertility or reproduction. Clinical data do not suggest that GAVISCON LIQUID ANISEED has an effect on human fertility.

Driving and using machinery:

GAVISCON LIQUID ANISEED has no or negligible influence on driving or the ability to operate tools or machines.

Important information about some of the ingredients of GAVISCON LIQUID ANISEED:

High blood levels of calcium can occur following the regular use of calcium carbonate.

Taking other medicines with GAVISCON LIQUID ANISEED:

Large doses of GAVISCON LIQUID ANISEED may affect the absorption of other oral medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GAVISCON LIQUID ANISEED with these medicines may cause undesirable interactions.

A time-interval of 2 hours should be considered between GAVISCON LIQUID ANISEED intake and the administration of other medicinal products, especially tetracyclines, flouroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphates, and estramustine.

Please consult your doctor, pharmacist or other health professional for advice.

4. HOW TO TAKE GAVISCON LIQUID ANISEED

For oral use

SHAKE WELL BEFORE USE

Always take GAVISCON LIQUID ANISEED exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults and children over 12 years: 10 - 20 ml after meals and at bedtime.

Children under 12 years: Should be given only on medical advice

Renal insufficiency: Caution if highly restricted salt diet is necessary. (See "WARNINGS")

Duration of treatment: If symptoms do not improve after seven days, the clinical situation should be reviewed by a medical practitioner.

If you have the impression that the effect of GAVISCON LIQUID ANISEED is too strong or too weak, tell your doctor or pharmacist.

Do not share medicines prescribed for you with any other person.

If you take more GAVISCON LIQUID ANISEED than you should:

Very large doses may cause bloating. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forgot to take GAVISCON LIQUID ANISEED:

- If you miss a dose of this medicine and you are taking it regularly, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosage schedule. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

Like all medicines, GAVISCON LIQUID ANISEED can have side effects.

If any of the following minor side effects continue, are severe or bother you, speak to your doctor or pharmacist:

- Stomach cramps, flatulence

If any of the following side effects occur, speak to your doctor or pharmacist:

- Skin rash, hives, itching, problems with breathing

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STRONG AND DISPOSING GAVISCON LIQUID ANISEED

Store at or below 25°C in a dry place

Keep all medicines out of reach and sight of children.

Do not store in bathrooms.

Do not use after the expiry date stated on the bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION

Amber glass bottles containing 150 ml, 300 ml or 600 ml.

8. IDENTIFICATION

An opaque pink suspension with an odour of fennel.

9. REGISTRATION NUMBER

L/11.10/1

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd
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11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date on the registration certificate: 20 April 1979

Date of the most recently revised patient information leaflet: 17 January 2020

Please go to the link for access to the corresponding PI: <https://cpdcentre.co.za/product-inserts/Gaviscon-Liquid-Aniseed.pdf>

Zimbabwe	2013/16.1/4820 (HR)
Mauritius	R12208/02/14
Zambia	133/005 (GS)
Namibia	19/32.2/0017 (NS0)

SKEDULERINGSSTATUS: **S0**

NAAM, STERKTE EN DOSERINGSVORM:

GAVISCON LIQUID ANISEED Suspensie

Natrium alginaat 500 mg en natriumbikarbonaat 267 per 10 ml

Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir u.

Hierdie medisyne is beskikbaar sonder 'n voorskrif van 'n dokter, vir jou om 'n matige siekte te behandel.

Ongeag moet u steeds **GAVISCON LIQUID ANISEED** versigtig gebruik om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Dit mag nodig wees om dit weer te lees
- Vra u apteker indien u meer inligting of advies benodig
- Moet nie GAVISCON LIQUID ANISEED deel met enige ander persoon nie.
- Sien 'n dokter indien u simptome vererger of na 7 dae nie verbeter nie.

1. WAT GAVISCON LIQUID ANISEED BEVAT:

Elke 10 ml **GAVISCON LIQUID ANISEED** bevat natriumalginaat 500 mg en natriumbikarbonaat 267 mg.

Die ander bestanddele is natriumbikarbonaat, kalsiumkarbonaatkarbom, natriumsakkarien, vinkelgeur, eritrosien, natriumhidroksied en water.

Preserveermiddels: Metielhidroxybenzoate 0,4% m / v en Propylhydroxybenzoate 0,06% m / v.

Bevat versoeter (Natriumsakkarien 0,100% m/v)

2. WAARVOOR GAVISCON LIQUID ANISEED GEBRUIK WORD:

GAVISCON LIQUID ANISEED word gebruik vir die volgende kondisies: maag-refluks (terugvloei van maaginhoud in die slukderm), reflux-esofagitis (ontsteekte voedselpyp); sooibrand, insluitend sooibrand tydens swangerskap; en simptome wat geassosieer met maag-refluks insluitend hiatus hernia (uitsteek van spiëre deur 'n spierwand); opgeblaasheid (ophoping van gas in die maag of ingewande); epigastriese en retrosternale nood.

3. VOOR JY GAVISCON LIQUID ANISEED NEEM:

Moet nie GAVISCON LIQUID ANISEED neem:

- Indien jy hipersensitief (allergies) is vir natriumalginaat of enige ander bestanddele.

Bevat metielparahydroxybenzoate en propiel parahydroxybenzoate: mag allergiese reaksies veroorsaak (moontlik vertraag)

Wees veral versigtig met GAVISCON LIQUID ANISEED:

- Indien jy 'n hartsiekte of hoë bloeddruk het
- Indien jy steroïdes neem.
- Indien jy 'n niersiekte het, elektrolietwanbalanse (bv. Lae kalsiumvlakke) of sirrose van die lewer.
- Wees versigtig met die behandeling van pasiënte met hiperkalsemie, Nefrohalsinose, en herhalende kalsium wat nierstene bevat.

Die neem van GAVISCON LIQUID ANISEED met spys en drank:

Hierdie medisyne word gewoonlik geneem na maaltye en met slapenstyd

Swangerskap en borsvoeding:

GAVISCON LIQUID ANISEED word gebruik vir sooibrand tydens swangerskap.

Geen nuwe-effekte van **GAVISCON LIQUID ANISEED** is getoon in pasgebore babas/suigelinge van behandelde moeders nie. Gaviscon kan gebruik word tydens borsvoeding.

Indien u swanger is of u baba borsvoed terwyl jy hierdie medisyne neem, raadpleeg u dokter, apteker of ander professionele gesondheidswerker vir advies.

Vrugbaarheid:

GAVISCON LIQUID ANISEED het geen negatiewe effek op vrugbaarheid of voortplanting van ouer- of nageslag nie.

Kliniese data dui nie daarop dat **GAVISCON LIQUID ANISEED** 'n invloed op die vrugbaarheid van mense het nie.

Bestuur en gebruik van masjinerie:

GAVISCON LIQUID ANISEED het geen of 'n onbeduidende invloed op die bestuur of die vermoë om werktuie of masjinerie te beheer nie.

Belangrike inligting oor sommige van die bestanddele in GAVISCON LIQUID ANISEED:

Hoë bloedvlakke van kalsium kan voorkom na die gereelde gebruik van kalsiumkarbonaat.

Gebruik van ander medisyne saam met GAVISCON LIQUID ANISEED:

Groot dosisse van **GAVISCON LIQUID ANISEED** kan die opname van ander orale medisyne beïnvloed. As u op 'n gereelde basis ander medisyne neem, insluitend aanvullende of tradisionele medisyne, kan die gelyktydige gebruik van **GAVISCON LIQUID ANISEED** ongewenste interaksies veroorsaak. 'n tydsinterval van 2 ure behoort oorweeg te word tussen inname van **GAVISCON LIQUID ANISEED** en die toediening van ander medisinale produkte, veral tetrasikliene, fluorokinolone, ystersoute, skildklierhormone, chloorkien, bisfosfonate en estramustien.

Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies.

4. Hoe om GAVISCON LIQUID ANISEED te gebruik

Vir orale gebruik

SKUD GOED VOOR GEBRUIK

Neem altyd Gaviscon Advance peperment presies soos in die pamflet beskryf word, of soos deur u dokter, apteker of verpleegkundige aanbeveel is. Raadpleeg u dokter, apteker of verpleegster as u nie seker is nie. Die gewone dosis is:

Volwassened en kinders oor 12 jaar: 10 - 20 ml na maaltye en met slapenstyd

Kinders jonger as 12 jaar: Moet slegs op mediese advies gegee word.

Nier gebrekkigheid: Wees bedag as 'n baie beperkte sout dieet nodig is. (sien "WAARSKUWINGS")

Duur van behandeling: Indien simptome nie na sewe dae verbetering toon nie, moet die kliniese situasie deur 'n mediese praaktisyn geassesseer word.

Indien jy die indruk verkry dat die effekte van **GAVISCON LIQUID ANISEED** te sterk of te swak is, raadpleeg u dokter of apteker.

Indien jy meer **GAVISCON LIQUID ANISEED** inneem as wat jy behoort:

Groot dosisse mag opgeblasenheid veroorsaak. In die geval van oordosering, raadpleeg u dokter of apteker.

Indien daar nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om GAVISCON LIQUID ANISEED te neem:

- As u 'n dosis medisyne mis en u neem dit gewoonlik op 'n gereelde basis, neem dit sodra u onthou. Indien dit byna tyd is vir die volgende dosis, slaan die gemiste dosis oor en keer terug na u normale dosisskedule. Moenie 'n dubbele dosis neem om op te maak vir die vergete dosisse nie.

5. MOONTLIKE NEWE-EFFEKTE

Soos alle medisyne, kan **GAVISCON LIQUID ANISEED** nuwe-effekte hê:

Indien enige van die volgende geringe nuwe-effekte voortduur, ernstig is of plaend word, raadpleeg u dokter of apteker:

- Maagkrampe, opgeblasenheid

Indien enige van die volgende nuwe-effekte voorkom, raadpleeg u dokter of apteker:

- Veluitslag, galbulte, jeukerigheid, probleme met asemhaling

Nie alle nuwe-effekte wat vir hierdie medisyne aangemeld word, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger tydens die gebruik van hierdie medisyne, raadpleeg u dokter, apteker of ander professionele gesondheidswerker vir advies.

6. BERGINGS-AANWYSINGS EN VERWYDERING VAN GAVISCON LIQUID ANISEED

Bewaar teen of benede 25 °C in 'n droë plek

Hou alle medisyne buite die bereik en sig van kinders.

Moenie in badkamers stoor nie.

Moet nie die produk gebruik na verloop van die vervaldatum wat op die bottel aangedui word nie.

Besorg alle ongebruikte medisyne terug aan u apteker.

Moet nie wegdoen met ongebruikte medisyne in dreine en rioolstelsels (bv. Toilette) nie.

7. AANBIEDING

Amberglasbottels wat 150 ml, 300 ml of 600 ml bevat.

8. IDENTIFIKASIE

'n pienk suspensie met 'n finkelagtige geur.

9. REGISTRASIENOMMER

L/11.10/1

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

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11. DATUM VAN PUBLIKASIE VAN DIE PASIËNT-INLIGTINGSVOUBILJET

Datum op die registrasiesertifikaat: 20 April 1979

Datum op die mees onlangste pasiënt-inligtingsvoubiljet: 17 Januarie 2020

Gaan asseblief na die web adres vir die ooreenstemmende professionele informasie:

<https://cpdcentre.co.za/product-inserts/Gaviscon-Liquid-Aniseed.pdf>