PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Gastronol

COMPLEMENTARY MEDICINE

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

SCHEDULING STATUS
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1 NAME OF THE MEDICINE
A.VOGEL GASTRONOL (tablets)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

Aesculus hippocastanum L. *(Aesculus hippocastanum)*	D4	40 mg
Aluminium oxide (Alumina)	D8	40 mg
Silver nitrate *(Argentum nitricum)*	D4	40 mg
Strychnos nux-vomica L. *(Nux vomica)*	D4	40 mg
Bryonia species *(Bryonia alba)*	D4	20 mg
from: *Bryonia cretica* L. subsp. *Dioica* (Jacq.) Tutin or *Bryonia alba* L.		
Citrullus colocynthis (L.) Schrad. (Colocynthis)	D4	20 mg

Contains sugar: Lactose ..... 200 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Round, biconvex, odourless, white tablets.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
A.VOGEL GASTRONOL is a homeopathic medicine which assists in the treatment of abdominal cramps, bloating, flatulence and diarrhoea.

4.2 Posology and method of administration
Posology
Adults and children over 12 years:
Take 2 to 3 tablets 3 to 5 times daily.

Special populations
Elderly population:
No dosage adjustment is required for this population.

Paediatric population
Children 6 – 12 years:
Take 1 tablet 3 to 5 times daily.

Method of administration
For oral use only.
Chew or dissolve in the mouth.
Acute treatment: Take the recommended dose every 15 – 30 minutes.
Maximum 5 doses / 24 hours.

4.3 Contraindications
- A.VOGEL GASTRONOL should not be used in patients who have a hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
- If the condition worsens, or if symptoms persist for more than 2 days, consult a doctor, pharmacist or other healthcare professional.

Lactose warning:
- A.VOGEL GASTRONOL contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take A.VOGEL GASTRONOL.

Paediatric population
- Abdominal cramps, bloating, flatulence and diarrhoea in children under 6 years should be evaluated by a healthcare professional, therefor A.VOGEL GASTRONOL is not recommended for use in children under 6 years of age, unless under medical supervision.

4.5 Interaction with other medicines and other forms of interaction
None known.

4.6 Fertility, pregnancy and lactation
Women of childbearing potential/Contraception in males and females
No information available.

Pregnancy
No information available.
Although no specific safety studies on the use of A.VOGEL GASTRONOL in pregnancy have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy, however please consult a doctor, pharmacist or healthcare provider for further advice.

Breastfeeding
No information available.
Although no specific safety studies on the use of A.VOGEL GASTRONOL in breastfeeding have been conducted, homeopathic remedies are generally considered to be suitable for use during breastfeeding, however please consult a doctor, pharmacist or healthcare provider for further advice.

Fertility
Fertility studies have not been performed.
No effect on fertility is expected.

4.7 Effects on ability to drive and use machines
A.VOGEL GASTRONOL has no known effect on mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects
If symptoms of hypersensitivity occur e.g. rash, urticaria or angioedema of the skin, discontinue use of product, and contact a healthcare professional immediately.

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. Healthcare providers are asked to report any suspected adverse reactions 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

4.9 Overdose
In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
Treatment of overdose should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Homeopathy D33.2
Has traditionally been used according to homeopathic principles.

5.2 Pharmacokinetic properties
No information available.

5.3 Preclinical safety data
No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose
Lactose
Magnesium stearate

Contains sugar:
Lactose ..... 200 mg

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C in a cool, dry place.
Protect from light.
Store in the original package/container.

6.5 Nature and contents of container

Amber glass bottles (type III glass), with a tamper evident seal and closed with a polypropylene cap, fitted with a liner.

Pack size: 200 tablets

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)/REFERENCE NUMBER

U 622 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

August 2022