

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

BIOGEN ACID CLEAR

Alfalfa/Birch/Celery/Devil's claw/Moringa/Nettle/Willow.

Sugar Free.

Contains ethyl alcohol: 50% v/v

D 33.6 Western Herbal Medicine, Complementary Medicine

Health supplements are intended only to complement health or supplement the diet.

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

Read all of this leaflet carefully because it contains important information for you. BIOGEN ACID CLEAR is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use BIOGEN ACID CLEAR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN ACID CLEAR with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What BIOGEN ACID CLEAR is and what it is used for.
2. What you need to know before you take BIOGEN ACID CLEAR.
3. How to take BIOGEN ACID CLEAR.
4. Possible side effects.
5. How to store BIOGEN ACID CLEAR.
6. Contents of the pack and other information.

1. What BIOGEN ACID CLEAR is and what it is used for

BIOGEN ACID CLEAR, a blend of botanical extracts supporting healthy uric acid levels. May lower symptoms associated with high uric acid levels such as joint, muscle or nerve discomfort, gout, and urinary tract inflammation.

2. What you need to know before you take BIOGEN ACID CLEAR

Do not take BIOGEN ACID CLEAR:

- If you are hypersensitive (allergic) to Alfalfa, Birch, Celery, Devil's Claw, Moringa, Nettle, Willow or to any of the other ingredients in BIOGEN ACID CLEAR (listed in section 6).
- If you are a woman of childbearing age, planning pregnancy, or if you are pregnant, or breastfeeding.
- If you have an autoimmune disease such as systemic lupus erythematosus, as Alfalfa may exacerbate inflammation.
- If you have impaired heart or kidney function.

Warnings and precautions

- Use with caution if you have a bleeding disorder, or if you are using blood thinners.
- Use with caution if you are taking birth control medication.
- Use with caution if you have hormone sensitive conditions or if you are undergoing hormone replacement therapy (HRT).
- Use with caution if you have high blood pressure.
- Use with caution if you have a thyroid disorder, as BIOGEN ACID CLEAR may theoretically affect thyroid levels.
- Use with caution if you have any heart disorders.
- Use with caution if you have gallstones.
- Use with caution if you have stomach ulcer disease.
- Use with caution if you have low blood pressure.
- Discontinue use at least 2 weeks prior to elective surgical procedures.
- Use with caution if you have diabetes.
- Avoid / use with caution if you are hypersensitive to aspirin.
- Use with caution if you have asthma.
- Use with caution if you have gout.
- Use with caution if you have hemophilia (abnormal blood clotting) and hypoprothrombinemia (deficiency of the blood-clotting substance prothrombin).
- Use with caution if you have liver disease.
- Not to be given to children under the age of 18 years (see section 4.8 d).

Children and adolescents

BIOGEN ACID CLEAR is not recommended for use in children.

Other medicines and BIOGEN ACID CLEAR

Always tell your healthcare provider if you are taking other medicines, including complementary or traditional medicines.

Consult your doctor if you want to take BIOGEN ACID CLEAR in combination with medicines or treatments such as:

- Acetylsalicylic acids, as Willow might increase the effect and adverse effects of aspirin.
- Blood thinners, as Alfalfa and Nettle may decrease the effect of blood thinners, whereas Celery, Willow, and Devil's claw may theoretically increase the risk of bleeding.
- Antidepressants, as Celery may theoretically increase blood levels of venlafaxine.
- Blood pressure lowering medication, as Moringa may theoretically have additive adverse effects when using concomitantly with acetazolamide.
- Carbonic anhydrase inhibitors, as Willow may theoretically increase the level of medicine metabolised by cytochrome P450 1A2 (CYP1A2), whereas Devil's claw and Moringa may increase the level of medicine metabolised by cytochrome P450 2C19 (CYP2C19) and 2C9 (CYP2C9).
- Diuretics, as Birch and Nettle may have additive diuretic effects.
- H2 blockers (reduce stomach acid production), as Devil's claw may theoretically decrease the effectiveness of H2-blockers.
- Hormone replacement therapy (HRT), as Alfalfa has estrogenic properties and may increase cancer cell growth.
- Blood glucose lowering medication, as Alfalfa, Moringa or Nettle may theoretically, have an additive blood glucose lowering effects.
- Immunosuppressants, as Alfalfa might theoretically decrease the efficacy of immunosuppressive therapy.
- Metals, as Celery and Nettle may theoretically reduce excretion and increase levels of lithium.
- Minerals, as Alfalfa may decrease the absorption of iron when using concomitantly.
- Photosensitising medicine, as Alfalfa and Celery may theoretically increase the risk for adverse effects.
- Proton pump inhibitors (PPIs), as Devil's claw may theoretically decrease the effectiveness of PPIs.
- Salicylates, as Willow may increase the effects and adverse effects of salicylate-containing medicine such as salsalate and choline magnesium trisalicylate.
- Thyroid hormones, as Moringa may theoretically reduce the effectiveness of synthetic thyroxine (T4) products, such as levothyroxine.
- Vitamins, as Alfalfa may affect the absorption of Vitamin E when using concomitantly.

Interactions with Diseases/Impairments

Aspirin hypersensitivity: Willow contains salicin and should be avoided/used with caution in patients with aspirin hypersensitivity.

Asthma: Willow contains salicin and should be avoided/used with caution in patients with asthma.

Autoimmune diseases: Alfalfa might exacerbate autoimmune diseases, such as systemic lupus erythematosus, multiple sclerosis (MS), rheumatoid arthritis (RA) by stimulating disease activity.

Bleeding disorders: Celery and Willow may theoretically increase the risk of bleeding.

Blood clotting disorders: Willow contains salicin and should be avoided/used with caution in patients with hemophilia (abnormal blood clotting) and hypoprothrombinemia (deficiency of the blood-clotting substance prothrombin).

Diabetes: Theoretically, Moringa may decrease blood glucose levels in patients with diabetes – use with caution if patient is on insulin or oral blood glucose lowering medication. Willow contains salicin and should be avoided/used with caution in patients with diabetes.

Gallstones: Devil's claw may increase bile production, which may affect patients with gallstones.

Gout: Willow contains salicin and should be avoided/used with caution in patients with gout.

Heart disorders: Devil's claw may affect patients with heart conditions, as it can affect heart rate, contractility of the heart, and blood pressure. Birch may have diuretic properties and should be used with caution in patients with impaired heart function where reduced fluid intake is recommended.

High blood pressure: Theoretically, Birch may increase sodium retention and worsen high blood pressure.

Hormone sensitive cancers/conditions: Theoretically, Alfalfa may have estrogenic effects and should be avoided in patients with hormone sensitive diseases such as cancers, endometriosis and uterine fibroids (noncancerous growths of the uterus).

Hypotension: Devil's claw may cause or exacerbate hypotension (abnormally low sodium levels) by increasing excretion of sodium.

Kidney dysfunction: Theoretically, Willow might worsen kidney function in patients with compromised kidney function, consequently resulting in kidney failure. Birch may have diuretic properties and should be used with caution in patients with impaired kidney function where reduced fluid intake is recommended.

Liver disease: Willow contains salicin and should be avoided/used with caution in patients with liver disease.

Low blood pressure: Theoretically, Moringa may increase the risk of low blood pressure.

Perioperative: Willow has antiplatelet properties, which may result in excessive bleeding if used perioperatively. Discontinue use at least 2 weeks prior to elective surgical procedures.

Stomach ulcer disease: Devil's claw may increase gastric acid secretion, consequently affecting patients with stomach ulcers. Willow contains salicin and should be avoided/used with caution in patients with stomach ulcers.

Thyroid disorders: Celery may theoretically affect thyroid levels in patients with thyroid disorders. Moringa may decrease the effectiveness of thyroid hormone levels, or further reduce thyroid hormone levels in patients with hypothyroidism (underactive thyroid) or subclinical hypothyroidism (early, mild form of underactive thyroid).

BIOGEN ACID CLEAR with food and drink

Unknown.

Pregnancy and breastfeeding

Not recommended for use during pregnancy and lactation.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent of BIOGEN ACID CLEAR may interfere with the daily activities of a patient. It is possible that BIOGEN ACID CLEAR would affect the ability to drive or operate machinery, as it may cause headache and dizziness. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which of BIOGEN ACID CLEAR affects them.

3. How to take BIOGEN ACID CLEAR

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

Always take BIOGEN ACID CLEAR exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are unsure.

Adults: Take 2.5 mL or 30 drops BIOGEN ACID CLEAR in a glass of water 3 times daily.

SHAKE WELL BEFORE USE.

If you take more BIOGEN ACID CLEAR than you should

Alfalfa, Birch, Celery, Moringa, Nettle and Willow - Insufficient reliable information.

Devil's claw - High doses of Devil's Claw root extract induced contractions in isolated uterine muscle from pregnant and nonpregnant rats.

Side effects listed in section 4 can be precipitated and/or be of increased severity.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BIOGEN ACID CLEAR

Always take BIOGEN ACID CLEAR as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIOGEN ACID CLEAR can have side effects:

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

Not all side effects reported for BIOGEN ACID CLEAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN ACID CLEAR, please consult your healthcare provider for advice.

Side effects associated with BIOGEN ACID CLEAR:

Frequent:

- Allergic skin reaction, and photosensitivity.
- Abdominal discomfort, constipation, diarrhoea, indigestion, flatulence, heartburn and vomiting.
- Sweating.

Less frequent:

- Skin irritation, patches of darker skin and itching.
- Anorexia, acid reflux, gastrointestinal bleeding, loss of taste, and Itching/burning in the throat.
- Severe allergic reaction, and upper airway mucosal build-up.
- Dizziness and headache.
- Swollen eyes.
- Anxiety.
- Reduced kidney blood flow.

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects 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>. By reporting side effects, you can help provide more information on the safety of BIOGEN ACID CLEAR.

5. How to store BIOGEN ACID CLEAR

Store in a cool, dry place at or below 25 °C.

Keep the bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN.

Return all unused BIOGEN ACID CLEAR to your pharmacist. Do not dispose of unused BIOGEN ACID CLEAR in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIOGEN ACID CLEAR contains:

The active ingredients (tincture) per 2.5 mL are:

Apium graveolens L. (Celery) [seed] 27,00 mg

Betula pendula Roth (Birch) [leaf] 18,00 mg

Harpagophytum procumbens (Burch.) DC. Ex Meisn. (Devil's Claw) [root] 18,00 mg

Medicago sativa L. (Alfalfa) [leaf] 18,00 mg

Salix alba L. (Willow) [bark] 18,00 mg

Urtica dioica L. (Nettle) [leaf] 18,00 mg

Moringa oleifera Lam. (Moringa) [leaf] 10,00 mg

Other ingredients are: Ethyl alcohol (50% v/v) and water.

Sugar free.

What BIOGEN ACID CLEAR looks like and contents of the pack

100 mL brown liquid in an amber glass bottle with a slow-flow dropper and a white cap.

Holder of Certificate of Registration and Manufacturer

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This leaflet was last revised in

October 2022.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

BIOGEN ACID CLEAR

Berk/Brandnetel/Duiwelskluu/Lusern/Moringa/Seldery/Wilgerboom.

Sukkervry.

Bevat etanol/koolstof.

D 33.6 Westerse Krui Medisyne. Komplementêre Medisyne

Gesondheidsaanvullings diens slegs as aanvulling tot gesondheid of dieet.

Hierdie ongeregtigste medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. BIOGEN ACID CLEAR is beskikbaar sonder 'n dokter se voorskrif om gesondheid te ondersteun. U moet egter steeds BIOGEN ACID CLEAR versigtig gebruik om die beste resultate daarvan te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie BIOGEN ACID CLEAR met enige ander persoon deel nie.
- Indien u verdere inligting of advies vrag, vra asseblie u gesondheidsorgwerker of apoteker.
- U moet 'n dokter raadpleeg indien u slomptoe verger of nie verbeter nie.

Wat is in hierdie voubliket

1. Wat BIOGEN ACID CLEAR is en waaroor dit gebruik word.
2. Wat u moet weet voor u BIOGEN ACID CLEAR neem.

Moenie BIOGEN ACID CLEAR neem nie:

- Indien u hipersensitief (allergies) is vir Berk, Brandnetel, Duiwelskluu, Lusern, Moringa, Seldery, Wilgerboom of enige van die ander bestanddele in BIOGEN ACID CLEAR.
- Indien u van uitbare ouderdom is, van plan is om 'n baba te hê, of reeds swanger is en borsvoed.
- Indien u 'n auto-immuun siekte soos sistemeuse lupus erythematosus het, aangesien Lusern inflammasie kan vererger.
- Indien u verswakte hart- of nierenfunsie het.

Waarskuwings en voorsorgmaatrels

- Gebruik versigtig indien u 'n bloedingsversteuring het, of indien u bloedverdunners gebruik.
- Gebruik versigtig indien u voorbeeldlike middels neem.
- Gebruik versigtig indien u hormoon sensitiviteit toestande het of indien u hormoonveranderingstherapie (HVT) ondergaan.
- Gebruik