PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX BERBERINE 1000mg hard capsules

Barberry root extract providing berberine hydrochloride 1 000 mg per daily dose (3 capsules, each containing 333,3 mg)
Sugar free

COMPLEMENTARY MEDICINE
Western Herbal Medicine
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

This leaflet is also available in Afrikaans on the product pages at https://genologix.co.za/product/genologix-berberine-1000mg-30-days-supply/ (30-day pack) and https://genologix.co.za/product/genologix-berberine-1000mg-bulk-120-days-supply/ (120-day pack).

Read all of this leaflet carefully because it contains important information for you

Genologix Berberine 1000mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix Berberine 1000mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Berberine 1000mg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Genologix Berberine 1000mg is and what it is used for
2. What you need to know before you take Genologix Berberine 1000mg
3. How to take Genologix Berberine 1000mg
4. Possible side effects
5. How to store Genologix Berberine 1000mg
6. Contents of the pack and other information

1. What Genologix Berberine 1000mg is and what it is used for

Genologix Berberine 1000mg is a Western herbal medicine. It contains berberine, a natural yellow plant compound extracted from the root of barberry (Berberis vulgaris).

Genologix Berberine 1000mg:

- helps support healthy glucose metabolism in healthy adults.

Genologix Berberine 1000mg is not intended to treat diabetes. If you have diabetes, do not take it without first talking to your doctor.

2. What you need to know before you take Genologix Berberine 1000mg

Do not take Genologix Berberine 1000mg:

- if you are hypersensitive (allergic) to berberine or barberry or any of the other ingredients of Genologix Berberine 1000mg (listed in section 6).
- if you are pregnant or breastfeeding (see "Pregnancy, breastfeeding and fertility").

Warnings and precautions

Take special care with Genologix Berberine 1000mg. Talk to your doctor or pharmacist before taking it:

- if you have diabetes or take any medicine to lower your blood sugar, because your blood sugar may drop too low;
- if you have low blood pressure;
- if you have liver disease;
- if you take any medicine prescribed by your doctor, because berberine changes how the body breaks down many medicines (see "Other medicines and Genologix Berberine 1000mg").

Do not use Genologix Berberine 1000mg for longer than 3 months without consulting your health care provider.

Children and adolescents

Do not give Genologix Berberine 1000mg to children and adolescents under 18 years of age. Berberine can be harmful to newborn babies.

Other medicines and Genologix Berberine 1000mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Berberine can change how the body breaks down many medicines, which may increase their effects and side effects. Talk to your doctor or pharmacist before you take Genologix Berberine 1000mg if you take:

- medicine for diabetes (e.g. metformin, insulin or sulphonylureas), because blood sugar may drop too low;
- cyclosporine or tacrolimus (medicines used after organ transplants);
- medicine for high blood pressure;
- medicine to thin the blood (e.g. warfarin);
- sedatives or sleeping tablets;
- any other prescription medicine.

Genologix Berberine 1000mg with food, drink and alcohol

Take Genologix Berberine 1000mg 30 minutes before food (see section 3). No interactions with drinks or alcohol are known.

Pregnancy, breastfeeding and fertility

Do not take Genologix Berberine 1000mg if you are pregnant or breastfeeding. Berberine can pass to the unborn baby and into breast milk, and may harm newborn babies.

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 health care provider for advice before taking this medicine.

Driving and using machines

Genologix Berberine 1000mg is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent Genologix Berberine 1000mg may interfere with your daily activities. Do not drive, operate machinery or take part in activities that need you to be alert until you know how Genologix Berberine 1000mg affects you.

Genologix Berberine 1000mg contains

Genologix Berberine 1000mg contains no sugar and no sweeteners.

3. How to take Genologix Berberine 1000mg

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

Always take Genologix Berberine 1000mg exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (18 years and older): take one (1) capsule three (3) times a day, 30 minutes before food. Three capsules provide 1 000 mg of berberine hydrochloride.

Do not take more than three (3) capsules in 24 hours.

Children and adolescents under 18 years: do not give Genologix Berberine 1000mg to this age group.

How to take it:

1. Take one capsule 30 minutes before each main meal.
2. Swallow the capsule whole with a glass of water.
3. Stop taking Genologix Berberine 1000mg if you get any side effects (see section 4).

Do not use Genologix Berberine 1000mg for longer than 3 months without consulting your health care provider.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If you take more Genologix Berberine 1000mg than you should

If you take too many capsules, you may get stomach cramps, nausea, diarrhoea or constipation. If you also take medicine for diabetes, your blood sugar may drop too low (signs include shaking, sweating, hunger, confusion and a fast heartbeat).

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

If you forget to take Genologix Berberine 1000mg

If you forget a dose, skip it and take your next capsule before your next meal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Genologix Berberine 1000mg

You can stop taking Genologix Berberine 1000mg at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Berberine 1000mg can have side effects.

Not all side effects reported for Genologix Berberine 1000mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Berberine 1000mg, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Berberine 1000mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Genologix Berberine 1000mg. You may need urgent medical attention or hospitalisation.

If you take medicine for diabetes and you get signs of low blood sugar (shaking, sweating, hunger, confusion or a fast heartbeat), eat or drink something sugary and contact your doctor.

Tell your doctor if you notice any of the following:

Frequency unknown:

- constipation or diarrhoea,
- stomach cramps or pain,
- wind (flatulence) or bloating,
- nausea (feeling sick).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Genologix Berberine 1000mg.

You can also report side effects directly to Genologix by completing the side effect report form on our website at https://genologix.co.za/adr-form-page/, or by contacting us on 087 094 0594, WhatsApp 060 532 8317 or info@genologix.co.za.

5. How to store Genologix Berberine 1000mg

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Protect from light and moisture.
- Keep the capsules in the original pouch. Reseal the pouch tightly after each use.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the pouch.
- Do not use Genologix Berberine 1000mg if the pouch seal is broken or the capsules look damaged.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What Genologix Berberine 1000mg contains

The active substance is an extract of barberry root (Berberis vulgaris), standardised to berberine hydrochloride 97 %.

Active ingredient	Per capsule (dried herb equivalent)	Per daily dose, 3 capsules (dried herb equivalent)
Berberis vulgaris L. (barberry) [root, as 333,3 mg per capsule (1 000 mg per dose) of a 40:1 extract standardised to berberine hydrochloride 97 %]	13 333 mg	40 000 mg

The other ingredients are microcrystalline cellulose and hypromellose (the vegan capsule shell).

Microcrystalline cellulose is a plant fibre used as a filler. It makes sure that every capsule contains the correct amount of the active ingredient. These ingredients are not active ingredients. They are only used to help us make the capsules accurately and consistently.

What Genologix Berberine 1000mg looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a bright yellow powder. Berberine is naturally very bitter and may stain fabrics yellow.

The powder in the capsules comes from natural plant material, so its colour can vary from batch to batch. It may be lighter or darker. This is normal. It is caused by natural factors such as soil conditions, rainfall and the time of harvest. It does not affect the quality of the product.

Genologix Berberine 1000mg is available in two pack sizes: 90 capsules (30 daily doses of 3 capsules) and 360 capsules (120 daily doses). Both are packed in a resealable, laminated, light-protective pouch.

Holder of Certificate of Registration

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Registration number

Not applicable. Unregistered complementary medicine, Act 101/1965.

Access to the corresponding Professional Information

The Professional Information for Genologix Berberine 1000mg is available on request from Genologix on 087 094 0594 or info@genologix.co.za. Address your correspondence for the attention of the Responsible Pharmacist.