

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

NATIVA COMPLEX® BERBERINE PLUS capsule

Berberine hydrochloride, Chromium glycinate, *Camellia sinensis* (L.) Kuntz (green tea extract) [leaf, extract standardized to 95 % polyphenols].

Sugar and preservative free.

- Health Supplement: D.34.12 Health Supplements – Multiple substance formulation.
- A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. 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.

NATIVA COMPLEX® BERBERINE PLUS is available without a doctor's prescription. Nevertheless, you still need to use NATIVA COMPLEX® BERBERINE PLUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NATIVA COMPLEX® BERBERINE PLUS with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET

1. What NATIVA COMPLEX® BERBERINE PLUS is and what it is used for
2. What you need to know before you take NATIVA COMPLEX® BERBERINE PLUS
3. How to take NATIVA COMPLEX® BERBERINE PLUS
4. Possible side effects
5. How to store NATIVA COMPLEX® BERBERINE PLUS
6. Contents of the pack and other information

1. What NATIVA COMPLEX® BERBERINE PLUS is and what it is used for

NATIVA COMPLEX® BERBERINE PLUS is a health supplement that can assist the body with healthy metabolic function and balance. It contains active ingredients that can also assist to promote insulin sensitivity; support cardiovascular health; lower lipid levels in the blood and support healthy liver function.

Efficacy of support may vary between users. Consult a relevant healthcare provider before use if you suspect that you may have insulin resistance, high blood glucose levels or diabetes.

2. What you need to know before you take NATIVA COMPLEX® BERBERINE PLUS

Do not take NATIVA COMPLEX® BERBERINE PLUS:

- If you are hypersensitive (allergic) to any of the ingredients of NATIVA COMPLEX® BERBERINE PLUS (listed in section 6 **Contents of pack and other information**).
- If you are pregnant as NATIVA COMPLEX® BERBERINE PLUS contains berberine (see **Pregnancy and Breastfeeding**).
- If you have gastric and duodenal ulcers, cardiovascular disorders such as hypertension and arrhythmia or hyperthyroidism as NATIVA COMPLEX® BERBERINE PLUS contains *Camellia sinensis* (green tea).
- If you are taking any chronic medication do not use this product without consulting your medical practitioner.

Warnings and precautions

- Special care should be taken with NATIVA COMPLEX® BERBERINE PLUS. Consult a healthcare provider before use if you have:
 - Bleeding disorders;
 - liver disease; or
 - kidney disease.
- Stop use and consult a healthcare provider if you develop symptoms of liver dysfunction such as jaundice, stomach pain, dark urine, unusual sweating and tiredness, nausea, and/or loss of appetite as NATIVA COMPLEX® BERBERINE PLUS contains *Camellia sinensis* (green tea).
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and NATIVA COMPLEX® BERBERINE PLUS

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

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- Blood thinners (anticoagulant - or antiplatelet medication) e.g., warfarin, as berberine and *Camellia sinensis* (green tea) may have a blood thinning effect increasing the risk of bleeding;
- antihypertensive medication, as the berberine in NATIVA COMPLEX® BERBERINE PLUS can increase their effects;
- antidiabetic medication, as the berberine, chromium and *Camellia sinensis* (green tea) in NATIVA COMPLEX® BERBERINE PLUS can cause hypoglycaemia; or
- central nervous system depressant medication, as the berberine in NATIVA COMPLEX® BERBERINE PLUS can increase their effects.

Taking NATIVA COMPLEX® BERBERINE PLUS with food, drink and alcohol

There is no known interaction between contents of NATIVA COMPLEX® BERBERINE PLUS and food, drink and alcohol.

Pregnancy, breastfeeding and fertility

Do not use NATIVA COMPLEX® BERBERINE PLUS if you are pregnant or breastfeeding as safety has not been established. Berberine crosses the placenta and can be transferred via breastmilk.

Driving and using machines

NATIVA COMPLEX® BERBERINE PLUS should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

It is not always possible to predict to what extent NATIVA COMPLEX® BERBERINE PLUS may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which NATIVA COMPLEX® BERBERINE PLUS affects you.

3. How to take NATIVA COMPLEX® BERBERINE PLUS

Do not share medicines with any other person.

Always take NATIVA COMPLEX® BERBERINE PLUS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

The usual dose for adults 18 years and older is:

Take one (1) capsule two (2) to three (3) times per day, with a glass of water, 30 minutes before meals or as directed by a healthcare provider.

If you take more NATIVA COMPLEX® BERBERINE PLUS than you should

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

If you forget to take NATIVA COMPLEX® BERBERINE PLUS

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking NATIVA COMPLEX® BERBERINE PLUS

If you are taking the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

NATIVA COMPLEX® BERBERINE PLUS can have side effects.

Not all side effects reported for NATIVA COMPLEX® BERBERINE PLUS are included in this leaflet. Should your general health worsen while or if you experience any untoward effects vs side effects while taking NATIVA COMPLEX® BERBERINE PLUS, please consult your healthcare provider for advice.

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to NATIVA COMPLEX® BERBERINE PLUS. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any of the following:

Frequency unknown:

- Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria (hives), skin rash and itching.
- Headache, insomnia, irritability, mood changes.
- Abdominal discomfort, bloating, constipation, diarrhoea, indigestion, flatulence (gas), nausea, vomiting.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “**Adverse drug reaction and quality**” website, found online at: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of NATIVA COMPLEX® BERBERINE PLUS.

5. How to store NATIVA COMPLEX® BERBERINE PLUS

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What NATIVA COMPLEX® BERBERINE PLUS contains

Active ingredients	Per capsule	Per maximum daily dose (3 capsules)	% NRV* per maximum daily dose (3 capsules)
Berberine (Berberine hydrochloride)	500 mg	1500 mg	*
Chromium Glycinate Providing: Chromium (elemental) Glycine	300 µg 30 µg 270 µg	900 µg 90 µg 810 µg	2 % * *
<i>Camellia sinensis</i> (L.) Kuntze (Green tea extract) [leaf, extract standardized to 95 % polyphenols]	25 mg	75 mg	*

*Nutrient reference values for adults and children older than 4 years.

*NRV not established.

The other ingredients or excipients are: gelatine capsule (capsule constituents: bovine gelatine, colourants, titanium dioxide), microcrystalline cellulose, magnesium stearate, maize starch.

NATIVA COMPLEX® BERBERINE PLUS is sugar and preservative free.

What NATIVA COMPLEX® BERBERINE PLUS looks like and contents of the pack

NATIVA COMPLEX® BERBERINE PLUS are orange capsules, available in a white plastic container with an orange flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.

Holder of Certificate of Registration

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This leaflet was last revised in

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

NATIVA COMPLEX® BERBERINE PLUS Professional Information may be obtained from the Nativa website (www.nativa.co.za).