

PATIENT INFORMATION LEAFLET: SFERA BERBERINE

SCHEDULING STATUS **[S0]**

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

SFERA BERBERINE. Each capsule contains: 500mg *Berberis aristata* (Indian barberry) [root, extract standardised for a minimum of 97% Berberine Hydrochloride] Suitable for vegetarians and vegans.
No added sugar.

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT - AYURVEDIC /UNANI MEDICINE

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 **SFERA BERBERINE** is available without a doctor's prescription, for you to use to supplement treatment of a mild illness. Nevertheless, you still need to use **SFERA BERBERINE** carefully to get the best results from it.

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

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1. What **SFERA BERBERINE** is and what it is used for

SFERA BERBERINE may support glucose metabolism and healthy blood sugar levels. **SFERA BERBERINE** may assist in carbohydrate metabolism. **SFERA BERBERINE** may support healthy liver function. **SFERA BERBERINE** may help to maintain healthy cholesterol levels by potentially reducing triglycerides and serum cholesterol.

2. What you need to know before you use **SFERA BERBERINE**

Do not take **SFERA BERBERINE**

- If you are hypersensitive (allergic) to any of the ingredients of **SFERA BERBERINE** (see section 6)

Warnings and precautions

Take special care with **SFERA BERBERINE**

- if you have diabetes.
- if you have cardiovascular disease.
- If you have kidney irritation, nephritis (inflamed kidneys).
- If you have liver toxicity.
- if you have a medical condition or are taking prescription medication.

Consult a health care provider if symptoms persist or worsen.

Children and adolescents

Children and adolescents under the age of 18 years should not take **SFERA BERBERINE**.

Other medicines and **SFERA BERBERINE**

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines). Consult a health care provider prior to use if you are taking blood thinners, anti-epileptic medication, and cyclosporine.

SFERA BERBERINE may decrease the efficacy of tetracycline or any other agents with antibacterial activity.

SFERA BERBERINE may lower blood sugar levels, Caution is advised when using medications that may also lower blood sugar.

SFERA BERBERINE may decrease total and LDL cholesterol, as well as triglycerides. Caution is advised in patients taking any cholesterol-lowering agents.

SFERA BERBERINE may decrease the metabolism of vitamin B; the concomitant use of berberine with vitamin B should be avoided.

SFERA BERBERINE with food and drink

Take **SFERA BERBERINE** with liquid with a meal.

Pregnancy and breastfeeding

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 machinery

It is not always possible to predict to what extent **SFERA BERBERINE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **SFERA BERBERINE** affects them.

3. How to take **SFERA BERBERINE**

Do not share medicines you are taking with any other person.

Always take **SFERA BERBERINE** exactly as described in this leaflet or as your doctor, pharmacist, or health care provider told you. Check with your doctor, pharmacist, or health care provider if you are not sure.

The usual dose is:

Adults: Take one (1) capsule twice daily orally with a meal, or as directed by your health care provider.

If you take more **SFERA BERBERINE** than you should

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

If you forget to take a dose of **SFERA BERBERINE**

Take your next dose at the normal time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SFERA BERBERINE can have side effects.

Not all side effect reported for **SFERA BERBERINE** are included in this leaflet.

Tell your doctor if you notice any of the following:

Side effect occurring less frequently: nausea, vomiting, skin irritation, facial flushing, hypertension, bradycardia or paraesthesia.

Should your general health worsen or if you experience any untoward effects while taking **SFERA BERBERINE**, please consult your health care provider for advice.

If any of the following happens, stop taking **SFERA BERBERINE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your 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 allergic reaction to **SFERA BERBERINE**. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- slowed heart rate.
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

• These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Uncommon/Less frequent side effects:

- nausea (feeling sick),
- headache,
- skin irritation
- facial flushing

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

Reporting of side effects

If you experience side effects, talk to your doctor or pharmacist. You can also report side effects to pharmacist@sfera-nutrition.co.za or 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 **SFERA BERBERINE**.

5. How to store **SFERA BERBERINE**

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from moisture.
- Keep in the original container until ready for use.
- Do not store in a bathroom.
- 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).

6. Contents of the pack and other information

What **SFERA BERBERINE** contains

Each capsule contains:

- *Berberis aristata* (Indian barberry) [root, extract standardised for a minimum of 97% Berberine Hydrochloride] 500 mg
- The other ingredients are: Vegetarian capsule, natural flowing agent and microcrystalline cellulose.

What **SFERA BERBERINE** looks like and contents of the pack

SFERA BERBERINE capsules are clear size "00" capsules filled with a brown powder. **SFERA BERBERINE:** 60 Capsules are packed into amber glass bottles, with golden lid, plastic seal liner, desiccant sachet, and outer protective tamperproof shrink sleeve on the cap.

Holder of Certificate of Registration

Sfera Bio Nutrition (Pty) Ltd.
5 Regency Drive, Block C, Route 21 Corporate Park, Pretoria, 0181
Telephone: 012 751 7117
Website: www.sfera-nutrition.co.za

This leaflet was last revised in

January 2024.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

Detailed information on this medicinal product is available from pharmacist@sfera-nutrition.co.za or www.sfera-nutrition.co.za

PASIËNT INLIGTINGSBLAD: SFERA BERBERINE

SKEDULERING STATUS SO

PRODUKNAAM, STERKE EN DOSEERVORM

SFERA BERBERINE. Elke kapsule bevat: 500mg *Berberis aristata* (Indian barberry) [wortel, uittreksel gestandaardiseer vir 'n minimum van 97% Berberienhidrochloried] Geskik vir vegetariërs en vegans. Geen suiker bygevoeg.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIE PRODUK – AYURVEDIC / UNANI MEDISYNE

Hierdie ongeregistreerde medisyne is nog nie geëvalueer deur die SAHPRA vir die kwaliteit, veiligheid of vir die voorgenome gebruik nie.

Lees die hele blaadjie noukeurig deur omdat dit belangrike inligting vir u bevat.

SFERA BERBERINE is beskikbaar sonder 'n dokter se voorskrif, vir u om te gebruik as ondersteuning vir behandeling van 'n ligte siekte. Nogtans moet **SFERA BERBERINE** met versigtigheid te gebruik word om die beste resultate daaruit te verkry.

- Hou hierdie blaadjie. U mag dit weer wil lees.
- Moenie **SFERA BERBERINE** deel met enige ander persoon nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Inhoud van hierdie blaadjie

1. Wat is **SFERA BERBERINE** en waarvoor word dit gebruik
2. Wat u moet weet voordat u **SFERA BERBERINE** gebruik
3. Hoe om **SFERA BERBERINE** te gebruik
4. Moontlike nuwe-effekte
5. Hoe om **SFERA BERBERINE** te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat is SFERA BERBERINE en waarvoor word dit gebruik

SFERA BERBERINE kan glukose metabolisme en gesonde bloedsuikervlakke ondersteun.

SFERA BERBERINE kan help met kooldraatmetabolisme.

SFERA BERBERINE kan help om gesonde lever funksie te ondersteun.

SFERA BERBERINE kan help om gesonde cholesterol te handhaaf deur moontlik trigliseriede en serumcholesterol te verlaag.

2. Wat u moet weet voordat u SFERA BERBERINE gebruik

Moenie SFERA BERBERINE neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA BERBERINE** (sien afdeling 6).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met SFERA BERBERINE:

- indien jy diabetes het.
 - indien jy kardiovaskulêre siekte het.
 - indien jy nierirritasie, nefritis (ontsteekte niere) het.
 - indien jy lewertoksiteit het.
 - indien u 'n mediese siekte het of voorskrif medisyne neem
- Raadpleeg u gesondheidsorgverskaffer indien die simptome aanhou of vererger.

Kinders en adolessente

Kinders en adolessente onder die ouderdom van 18 jaar moet nie **SFERA BERBERINE** gebruik nie.

Ander medisyne en SFERA BERBERINE

Vertel altyd jou gesondheidsorgverskaffer as u enige ander medisyne gebruik (dit sluit alles in komplementêre of tradisionele medisyne).

Raadpleeg 'n gesondheidsorgverskaffer voor gebruik indien u bloed verdunners (anti-koagulant), anti-epileptiese medikasie en siklosporien gebruik.

SFERA BERBERINE kan die doeltreffendheid van tetrasiklien of enige ander middels met antibakteriese aktiwiteit verminder.

SFERA BERBERINE kan bloedsuikervlakke verlaag. Omsigtigheid word aangeraai wanneer medikasie gebruik word wat ook bloedsuiker kan verlaag.

SFERA BERBERINE kan totale en LDL cholesterol, sowel as trigliseriede verlaag. Pasiënte wat enige cholesterolverlagende middels gebruik, word aangeraai om versigtig te wees.

SFERA BERBERINE kan die metabolisme van vitamien B verminder; die gelyktydige gebruik van berberien met vitamien B moet verniy word.

SFERA BERBERINE saam met voedsel en vloeistowwe

Neem **SFERA BERBERINE** met vloeistof saam met 'n maaltyd.

Swangerskap en borsvoeding

Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om swanger te raak, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer voordat u hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate **SFERA BERBERINE** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet toesien dat hulle nie aan bogenoemde aktiwiteite deelneem nie totdat hulle bewys is van die mate waarin **SFERA BERBERINE** hulle beïnvloed.

3. Hoe om SFERA BERBERINE te gebruik

Moenie medisyne wat u neem met enige ander persoon deel nie.

Neem altyd **SFERA BERBERINE** presies soos voorgeskryf in hierdie pamflet of soos u dokter, apteker of gesondheidsorgverskaffer vir u gesê het. Raadpleeg u dokter, apteker of gesondheidsorgverskaffer as u nie seker is nie.

Die gewone dosis is:

Volwassenes: Neem een (1) kapsule oraal, twee keer per dag met 'n maaltyd, of soos aangedui deur u gesondheidsorgverskaffer.

Indien u meer SFERA BERBERINE neem as wat u behoort te neem

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gif-hulp sentrum.

Indien u vergeet om 'n dosis SFERA BERBERINE te neem

Neem u volgende dosis op die gewone tyd. Moenie 'n dubbele dosis neem om die vergeete enkel dosis in te haal nie.

4. Moontlike nuwe-effekte

SFERA BERBERINE kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir **SFERA BERBERINE** gerapporteer is, word in hierdie inligtingsblad ingesluit nie.

Stel u dokter in kennis as enige van die volgende nuwe effekte voorkom:

Nuwe-effekte wat minder gereeld voorkom: naarheid, braking, velirritasie, gesigsoploei, hipertensie, bradikardie of parestesie. Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA BERBERINE** neem.

As enige van die volgende gebeur, moet u ophou om **SFERA BERBERINE** te neem en u dokter onmiddellik inlig of na die ongevallende afdeling in u naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- Uitslag of jeuk.
- Flou word.

Dit is alles baie ernstige nuwe-effekte. As u dit het, kan u 'n ernstige reaksie op **SFERA BERBERINE** gehad het. U mag dringende mediese hulp of hospitalisasie benodig. Vertel u dokter dadelik of gaan na die ongevallende afdeling by u naaste hospitaal as u enige van die volgende opmerk:

- veranderinge in die manier waarop u hart klop, byvoorbeeld, as u agterkom dat dit stadiger klop,
- vergeling van die vel en oë, donker urine en moegheid wat simptome van lewer probleme kan wees

Dit is alles ernstige nuwe-effekte. U benodig dalk dringende mediese hulp.

Vertel u dokter as u enige van die volgende opmerk:

Ongewone/minder gereelde nuwe-effekte:

- naarheid,
- hoofpyn,
- vel irritasie,
- velspeoeling.

Stel u dokter of apteker in kennis as u nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie.

Rapportering van nuwe-effekte

As u nuwe-effekte ervaar, moet u met u dokter of apteker praat. U kan ook nuwe-effekte aan pharmacist@sfera-nutrition.co.za of aan SAHPRA rapporteer via die

"6.04 Adverse Drug Reaction Reporting Form", aanlyn onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **SFERA BERBERINE** voorsien.

6. Inhoud van die verpakking en ander inligting

Wat SFERA BERBERINE bevat

Elke kapsule bevat:

- Berberis aristata* (Indian barberry) [wortel, uittreksel gestandaardiseer vir 'n minimum van 97% Berberienhidrochloried] 500mg
- Die ander bestanddele is: Vegetariese kapsules en mikrokristallyne sellulose.

Hoe SFERA BERBERINE lyk en die inhoud van die verpakking

SFERA BERBERINE kapsules is deursigtige grootte "00" kapsules gevul met 'n bruin poeier.

SFERA BERBERINE: 60 kapsules word verpak in 'n amber glasbottel, met 'n goudkleurige deksel met 'n druk-seël voering, silika gel sakkie en 'n beskermende selfoan krimp-seël voering.

Houer van Registrasiesertifikaat

Sfera Bio Nutrition (Pty) Ltd.
5 Regency Rylaan, Block C, Route 21 Corporate Park, Pretoria, 0181
Telefoon: 012 751 7117
Webwerf: www.sfera-nutrition.co.za

Hierdie pamflet is laas hersien in

Januarie 2024.

Registrasienommer

Sal geallokeer word deur SAHPRA tydens registrasie.

Toegang tot die ooreenstemmende professionele inligting

Getaliteerde inligting oor hierdie medisyne is beskikbaar by pharmacist@sfera-nutrition.co.za of www.sfera-nutrition.co.za