

ZéNERGI® EVENING PRIMROSE OIL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

50

Zénergi® Evening Primrose Oil
Evening primrose oil / Vitamin E
Contains sugar alcohol (8 mg sorbitol per capsule).

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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.

Zénergi® Evening Primrose Oil is available without a doctor's prescription. Nevertheless, you still need to take Zénergi® Evening Primrose Oil carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Zénergi® Evening Primrose Oil 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 Zénergi® Evening Primrose Oil is and what it is used for.
2. What you need to know before you take Zénergi® Evening Primrose Oil.
3. How to take Zénergi® Evening Primrose Oil.
4. Possible side effects.
5. How to store Zénergi® Evening Primrose Oil.
6. Contents of the pack and other information.

1. What ZÉNERGI EVENING PRIMROSE OIL is and what it is used for

ZÉNERGI EVENING PRIMROSE OIL provides essential fatty acids and vitamin E for the maintenance of good health.

2. What you need to know before you take Zénergi® Evening Primrose Oil

Do not take Zénergi® Evening Primrose Oil:

If you are hypersensitive (allergic) to evening primrose oil, vitamin E or any of the other ingredients of Zénergi® Evening Primrose Oil (see section 6).

Warnings and precautions

Take special care with Zénergi® Evening Primrose Oil if you have a bleeding disorder. You should stop taking Zénergi® Evening Primrose Oil at least 2 weeks before any surgical procedures.

Children

Zénergi® Evening Primrose Oil is not suitable for children.

Other medicines and Zénergi® Evening Primrose Oil

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

Tell your doctor or pharmacist if you are currently using anticoagulant medicines (used to prevent your blood from clotting) or herbal supplements with blood thinning effects.

Pregnancy, breastfeeding and fertility

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 Zénergi® Evening Primrose Oil. The safety of Zénergi® Evening Primrose Oil during pregnancy and breastfeeding has not been established.

Driving and using machines

Zénergi® Evening Primrose Oil is unlikely to affect your ability to drive a vehicle and use machines.

Zénergi® Evening Primrose Oil contains sorbitol

Zénergi® Evening Primrose Oil contains 8 mg sorbitol in each capsule.

3. How to take Zénergi® Evening Primrose Oil

Always take Zénergi® Evening Primrose Oil exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: Take 1 – 2 capsules daily with food or as directed by a health care provider.

Do not exceed the recommended dosage.

Consult a relevant health care provider for use beyond 6 months.

If you take more Zénergi® Evening Primrose Oil 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.

Take this leaflet and the remaining Zénergi® Evening Primrose Oil with you so the doctor will know what you have taken.

4. Possible side effects

Zénergi® Evening Primrose Oil can have side effects.

Not all side effects reported for Zénergi® Evening Primrose Oil are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Zénergi® Evening Primrose Oil, please consult your health care provider for advice.

If any of the following happens, stop taking Zénergi® Evening Primrose Oil 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 Zénergi® Evening Primrose Oil. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Pain in your stomach area, bloated stomach, diarrhoea, indigestion, flatulence (wind), nausea (feeling sick), vomiting (being 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 Zénergi® Evening Primrose Oil.

5. How to store Zénergi® Evening Primrose Oil

- Store at or below 25 °C, in a dry place away from direct sunlight.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Zénergi® Evening Primrose Oil contains

Each capsule contains:

<i>Oenothera biennis</i> L. (Evening Primrose) oil	500 mg
providing:	
Gamma-linolenic acid (GLA)	35 mg
Linoleic acid (LA)	300 mg
Vitamin E	10 IU (6,71 mg)

The other ingredients are the capsule shell (containing gelatine), glycerine, purified water, simethicone and sorbitol.

What Zénergi® Evening Primrose Oil looks like and contents of the pack

A clear, pale yellow, oval shaped capsule. Capsules are packed in white HDPE containers.

Pack sizes: 30, 60 and 90 capsules*.

*Not all pack sizes may be marketed.

Holder of certificate of registration

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Tel. no.: 011 848 3050

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July 2024.

Registration number

Will be allocated by SAHPRA upon registration.

ZéNERGI® EVENING PRIMROSE OIL

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

SO

Zénergi® Evening Primrose Oil kapsules
Aandblomolie / Vitamien E
Bevat suikeralkohol (8 mg sorbitol per kapsule).

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

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

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

Zénergi® Evening Primrose Oil is beskikbaar sonder 'n dokter se voorskrif, sodat jy dit vir instandhouding van jou gesondheid kan gebruik. Jy moet Zénergi® Evening Primrose Oil nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie Zénergi® Evening Primrose Oil met 'n ander persoon deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is Zénergi® Evening Primrose Oil en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy Zénergi® Evening Primrose Oil neem.
3. Hoe om Zénergi® Evening Primrose Oil te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Zénergi® Evening Primrose Oil te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is Zénergi® Evening Primrose Oil en waarvoor word dit gebruik

Zénergi® Evening Primrose Oil is 'n gesondheidsaanvulling wat omega-6-vetsure en linoleïensuur verskaf vir die handhawing van 'n goeie gesondheid.

2. Wat jy moet weet voordat jy Zénergi® Evening Primrose Oil neem

Moenie Zénergi® Evening Primrose Oil neem nie:

Indien jy hipersensitief (allergies) is vir nagblomolie, vitamien E of vir enige van die ander bestanddele van Zénergi® Evening Primrose Oil (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met Zénergi® Evening Primrose Oil indien jy 'n bloedingsteuring het. Hou ten minste 2 weke voor 'n chirurgiese prosedure (operasie) op om Zénergi® Evening Primrose Oil te neem.

Kinders:

Zénergi® Evening Primrose Oil is nie geskik vir kinders nie.

Ander medisyne en Zénergi® Evening Primrose Oil

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans antikoagulant/ antiplaattjemedisyne (gebruik om jou bloed te verdun), of kruid-aanvullings met bloedverdundende effekte gebruik.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy Zénergi® Evening Primrose Oil neem. Die veiligheid van Zénergi® Evening Primrose Oil gedurende swangerskap en borsvoeding is nog nie vasgestel nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat Zénergi® Evening Primrose Oil 'n invloed op jou vermoë om 'n voertuig te bestuur of masjiene te gebruik sal hê.

Zénergi® Evening Primrose Oil bevat sorbitol

Zénergi® Evening Primrose Oil bevat 8 mg sorbitol in elke kapsule.

3. Hoe om Zénergi® Evening Primrose Oil te neem

Neem Zénergi® Evening Primrose Oil altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou apteker vir jou aangewys het. Vra gerus jou apteker indien jy onseker is.

Die gebruikelike dosis is:

Volwassenes: Neem 1 – 2 kapsules daaglik met kos of soos aangedui deur jou gesondheidsorgverskaffer.

Moenie die aanbevole dosis oorskry nie.

Raadpleeg 'n relevante gesondheidsorgverskaffer indien jy dit vir langer as 6 maande wil gebruik.

Wat om te doen indien jy meer Zénergi® Evening Primrose Oil geneem het as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie pamflet en die res van die Zénergi® Evening Primrose Oil saam sodat die dokter weet wat jy geneem het.

4. Moontlike nuwe-effekte

Zénergi® Evening Primrose Oil kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir Zénergi® Evening Primrose Oil gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy Zénergi® Evening Primrose Oil neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om Zénergi® Evening Primrose Oil te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling.
- Uitslag of gejeuk.
- Floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op Zénergi® Evening Primrose Oil gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Nuwe-effekte wat gereeld voorkom:

- Maagpyn, opgeblaaide maag, diarree, slegte spysvertering, winderigheid, naarheid, braking.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eReporting-platform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is. Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van Zénergi® Evening Primrose Oil te verskaf.

5. Hoe om Zénergi® Evening Primrose Oil te bêre

- Bêre by of onder 25 °C, op 'n droë plek, weg van direkte sonlig.
- Bêre alle medisyne buite die bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die houer gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) wegdoen nie.

6. Inhoud van die pak en ander inligting

Wat Zénergi® Evening Primrose Oil bevat

Elke kapsule bevat:

Oenothera biennis L. (Nagblom) olie	500 mg
verskaf:	
Gamma-linoleensuur (GLA)	35 mg
Linoleïensuur (LA)	300 mg
Vitamien E	10 IE (6,71 mg)

Die ander bestanddele is die kapsule dop (bevat gelatien), gliserien, gesuiwerde water, simetikoon en sorbitol.

Hoe Zénergi® Evening Primrose Oil lyk en inhoud van die verpakking

'n Helder, liggeel, ovaalvormige kapsule.

Die kapsules word verpak in wit HDPE-houers.

Verpakkingsgrootte: 30, 60 en 90 kapsules*.

Nie al die verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat:

Biotech Laboratories (Edms.) Bpk.
Grondvloer, Blok K Wes, Central Park
400 16^{de} Straat, Ranjespark, Midrand, 1685
Suid Afrika
Tel. 011 848 3050

Hierdie inligtingsblad is laas hersien in Julie 2024.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.