

SOLAL® FLUSH-FREE NIACIN 35 MG

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

SOLAL® FLUSH-FREE NIACIN 35 mg, capsules

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

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

SOLAL® FLUSH-FREE NIACIN 35 mg is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SOLAL® FLUSH-FREE NIACIN 35 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SOLAL® FLUSH-FREE NIACIN 35 mg with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT SOLAL® FLUSH-FREE NIACIN 35 mg CONTAINS

The active substance is:

Inositol hexanicotinate (Vitamin B₃) 35,0 mg

The other ingredients are:

Colloidal silicone dioxide, hypromellose, magnesium stearate and microcrystalline cellulose.

WHAT SOLAL® FLUSH-FREE NIACIN 35 mg IS USED FOR

Category D Complementary Medicine

Discipline 34.11 Health Supplements: Vitamins

SOLAL® FLUSH-FREE NIACIN 35 mg helps to metabolise carbohydrates, fats and proteins. It contributes to the maintenance of normal mucous membranes and normal skin. Assists with normal psychological function and the reduction of tiredness and fatigue. It contributes to normal growth and development. A factor in the maintenance of good health.

BEFORE YOU TAKE SOLAL® FLUSH-FREE NIACIN 35 mg

Do not take SOLAL® FLUSH-FREE NIACIN 35 mg if you are hypersensitive (allergic) to any of the ingredients. This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Take special care with SOLAL® FLUSH-FREE NIACIN 35 mg

Patients with unstable angina (chest pain caused by reduced blood flow to the heart) should exercise caution before taking SOLAL® FLUSH-FREE NIACIN 35 mg.

Patients with bleeding disorders must take special care when using SOLAL® FLUSH-FREE NIACIN 35 mg.

If you must go for an operation, discontinue the use of SOLAL® FLUSH-FREE NIACIN 35 mg at least 2 weeks before elective surgical procedures.

If you suffer from allergies (hay fever, hives, conjunctivitis and reactions to insect bites or stings) take special care when using inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) as is it might increase allergies due to additive histamine release. Increased blood flow and reddening of the skin might occur.

Taking SOLAL® FLUSH-FREE NIACIN 35 mg with food and drink

Take SOLAL® FLUSH-FREE NIACIN 35 mg after food.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking SOLAL® FLUSH-FREE NIACIN 35 mg. Safety during pregnancy and breastfeeding has not been established.

Important information about some of the ingredients of SOLAL® FLUSH-FREE NIACIN 35 mg

Sugar free. Suitable for vegans and vegetarians.

Taking other medicines with SOLAL® FLUSH-FREE NIACIN 35 mg

Always tell your healthcare provider if you are taking any other medicine.

If you are on antidiabetic medication such as metformin, caution must be exercised as inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) may cause hyperglycemia (high glucose levels), abnormal glucose tolerance and/or glycosuria (the presence of glucose in the urine) and may diminish the effects of these antidiabetic drugs. Increased blood glucose monitoring may be necessary, particularly early in the course of treatment.

If you are on anticoagulant/antiplatelet medication (such as aspirin, warfarin and clopidogrel), consult a relevant healthcare provider as the use of these medications with inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) might increase the risk of bleeding and bruising.

HOW TO TAKE SOLAL® FLUSH-FREE NIACIN 35 mg

Do not share medicines prescribed for you with any other person. Always take SOLAL® FLUSH-FREE NIACIN 35 mg exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

The usual dosage is:

Adults: Take 1 capsule once daily after food.

If you take more SOLAL® FLUSH-FREE NIACIN 35 mg than you should

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 a dose of SOLAL® FLUSH-FREE NIACIN 35 mg

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

POSSIBLE SIDE EFFECTS

SOLAL® FLUSH-FREE NIACIN 35 mg can have side effects. Orally inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) is well tolerated. However, common side effects may include gastrointestinal upset, pain, constipation, diarrhea, flushing, heartburn, liver enzyme elevation, nausea and vomiting. Not all side effects reported for SOLAL® FLUSH-FREE NIACIN 35 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOLAL® FLUSH-FREE NIACIN 35 mg, please consult your healthcare provider for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF SOLAL® FLUSH-FREE NIACIN 35 mg

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package / container.

Keep the container tightly closed.

Protect from moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / bottle.

Do not use SOLAL® FLUSH-FREE NIACIN 35 mg if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF SOLAL® FLUSH-FREE NIACIN 35 mg

A white plastic container with a white plastic screw cap and a seal for protection, containing 60 capsules.

IDENTIFICATION OF SOLAL® FLUSH-FREE NIACIN 35 mg

A clear, SOLAL branded (black ink) capsule containing a white powder.

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

PROFESSIONAL INFORMATION

For further information refer to the Professional Information of the product.

NAME AND ADDRESS OF REGISTRATION HOLDER

Ascendis Consumer Brands (Pty) Ltd

1 Carey Street

Wynberg, Gauteng 2090

South Africa

+27 11 036 9420

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

TBA

SOLAL® FLUSH-FREE NIACIN 35 MG

PASIËNTINLIGTINGSBLAADJIE (Afrikaans)

SKEDULERINGSSTATUS

Ongeskeduleer

HANDELSNAAM EN DOSEERVORM

SOLAL® FLUSH-FREE NIACIN 35 mg, kapsules

Lees die hele inligtingsblaadjie noukeurig deur, dit bevat belangrike inligting vir jou

'n Dieët met verskeidenheid is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling sowel as geestelike en fisiese prestasies te bewerkstellig.

SOLAL® FLUSH-FREE NIACIN 35 mg is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egtër nogsteeds SOLAL® FLUSH-FREE NIACIN 35 mg versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voubljiet, dit mag dalk nodig wees om dit weer te lees.
- Moenie SOLAL® FLUSH-FREE NIACIN 35 mg met enige ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.

WAT SOLAL® FLUSH-FREE NIACIN 35 mg BEVAT

Die aktiewe bestanddeel is:

Inositol heksanikotinaat (Vitamin B₃) 35,0 mg

Die ander bestanddele is:

Kolloidale silikondioksied, hipromellose, magnesiumstearaat en mikrokristallyn sellulose.

WAARVOOR SOLAL® FLUSH-FREE NIACIN 35 mg GEBRUIK WORD

Kategorie D Komplementêre Medisyne

Dissipline 34.11 Gesondheidsaanvullings: Vitamien

SOLAL® FLUSH-FREE NIACIN 35 mg help om koolhidrate, vette en proteïene te metaboliseer. Dit dra by tot die instandhouding van normale slymvliese en normale vel. Help met normale psigologiese funksie en die vermindering van moegheid en uitputting. Dit dra by tot normale groei en ontwikkeling. 'n Faktor in die instandhouding van goeie gesondheid.

VOORDAT SOLAL® FLUSH-FREE NIACIN 35 mg GEBRUIK WORD

Moenie SOLAL® FLUSH-FREE NIACIN 35 mg gebruik indien jy hipersensitief (allergies) is vir enige van die bestanddele nie. Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Neem spesiale sorg met SOLAL® FLUSH-FREE NIACIN 35 mg

Pasiënte met onstabiele angina (borskaspynt wat veroorsaak word deur verminderde bloedvloei na die hart) moet versigtig wees voor die gebruik van SOLAL® FLUSH-FREE NIACIN 35 mg.

Pasiënte met bloedsversteurings moet spesiale sorg neem met die gebruik van SOLAL® FLUSH-FREE NIACIN 35 mg.

As jy 'n operasie moet ondergaan, staak die gebruik van SOLAL® FLUSH-FREE NIACIN 35 mg ten minste 2 weke voor elektiewe chirurgiese prosedures.

As jy aan allergieë ly (hoofkoors, korwe, konjunktivitis en reaksies op insekbyte of -stekte), neem spesiale sorg met die gebruik van inositol-hexanikotinaat (soos in SOLAL® FLUSH-FREE NIACIN 35 mg) aangesien dit allergieë kan verhoog as gevolg van bykomende histamien-vrystelling. Verhoogde bloedvloei en blosing van die vel kan voorkom.

Neem van SOLAL® FLUSH-FREE NIACIN 35 mg met voedsel en vloeistof

SOLAL® Neem FLUSH-FREE NIACIN 35 mg na voedsel.

Swangerskap en Borsvoeding

As jy swanger is of jou baba borsvoed, raadpleeg jou dokter, apteker of gesondheidsorgverskaffer voordat jy SOLAL® FLUSH-FREE NIACIN 35 mg gebruik.

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.

Belangrike inligting in verband met sommige van die bestanddele in SOLAL® FLUSH-FREE NIACIN 35 mg

Suikervry.

Geskik vir vegane en vegetariërs.

As jy ander medisyne saam met SOLAL® FLUSH-FREE NIACIN 35 mg neem

Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medisyne gebruik.

As jy op antidiabetiese medikasie soos metformin is, moet jy versigtig wees aangesien inositol-hexanikotinaat (soos in SOLAL® FLUSH-FREE NIACIN 35 mg) hiperglukemie (hoë bloedglukose

vlakke), abnormale glukose toleransie en/of glukosurie (die teenwoordigheid van glukose in die uriene) kan veroorsaak en die effekte van hierdie antidiabetiese middels verminder. Verhoogde monitering van bloedglukose mag nodig wees, veral vroeg in die verloop van behandeling.

As jy op antikoagulant/antiplaatjie medikasie is (soos aspirien, warfarin en klopidogrel), raadpleeg 'n relevante gesondheidsorgverskaffer aangesien die gebruik van hierdie medikasie met inositol-hexanikotinaat (soos in SOLAL® FLUSH-FREE NIACIN 35 mg) die risiko vir bloeding en kneusing kan verhoog.

HOE OM SOLAL® FLUSH-FREE NIACIN 35 mg TE GEBRUIK

Moenie jou medisyne met enige iemand anders deel nie. Neem SOLAL® FLUSH-FREE NIACIN 35 mg altyd presies soos aanbeveel. Besevig met jou dokter of apteker indien jy onseker is. Die normale dosering is:

Volwassenes: Neem 1 kapsule een keer daaglik na voedsel.

Indien jy meer SOLAL® FLUSH-FREE NIACIN 35 mg gebruik as wat jy behoort

Indien oordosering vermoed word, raadpleeg onmiddellik jou dokter of apteker. Indien geneene beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet het om SOLAL® FLUSH-FREE NIACIN 35 mg te neem

Moenie 'n dubbele dosis neem om vir oorgeslane dosisse te vergeet nie.

MOONTLIKE NEWE-EFFEKTE

SOLAL® FLUSH-FREE NIACIN kan moontlik newe-effekte veroorsaak.

Oraal word inositol-hexanikotinaat (soos in SOLAL® FLUSH-FREE NIACIN 35 mg) goed verdra. Maar algemene newe-effekte kan insluit gastroïntestinale ongesteldheid, pyn, konstipasie, diarree, blosing, soobrand, verhoogde lewensrieme, naarheid en braking.

Nie alle newe-effekte wat vir SOLAL® FLUSH-FREE NIACIN 35 mg aangemeld is, word in hierdie voubljiet genoem nie. Indien jou algemene gesondheid verswak of indien jy enige nadelige effekte ondervind terwyl jy SOLAL® FLUSH-FREE NIACIN 35 mg gebruik, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg.

Indien jy enige newe-effekte waarneem wat nie in hierdie voubljiet genoem word nie, moet jy jou dokter of apteker daarvan vertel.

BERGING EN WEGDOEN VAN SOLAL® FLUSH-FREE NIACIN 35 mg

Bewaar alle medikasie buite bereik van kinders.

Bewaar teen of benede 25 °C.

Bewaar in die oorspronklike houër.

Maak die houër dig toe.

Beskerm teen vog.

Moenie die produk in die badkamer bewaar nie.

Moenie na die vervaldatum wat op die etiket / bottel aangedui is, gebruik nie.

Moenie SOLAL® FLUSH-FREE NIACIN 35 mg gebruik indien jy enige sigbare tekens van produkafbraak opmerk nie.

Besorg enige ongebruikte medisyne terug aan jou apteker.

Moenie van ongebruikte medisyne ontslae raak in dreine of rioolstelsels nie (bv. toilette).

AANBIEDING VAN SOLAL® FLUSH-FREE NIACIN 35 mg

'n Wit plastiek houër met 'n wit plastiek skroefprop en 'n seël vir beskerming wat 60 kapsules bevat.

IDENTIFIKASIE VAN SOLAL® FLUSH-FREE NIACIN 35 mg

'n Deursigtige, SOLAL gemerkte (swart ink) kapsule wat 'n wit poeier bevat.

REGISTRASIEONMMER

TBA

DATUM VAN REGISTRASIE

TBA

PROFESIONELE INLIGTING

Verwys na die voubljiet met Professionele Inligting vir meer inligting.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Ascendis Consumer Brands (Pty) Ltd

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South Africa

+27 11 036 9420

DATUM VAN PUBLIKASIE VAN DIE PROFESIONELE INLIGTING

TBA

905M296/00

SOLAL® FLUSH-FREE NIACIN 35 MG

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

SOLAL® FLUSH-FREE NIACIN 35 mg, capsules

COMPOSITION

Each capsule contains: Inositol hexanicotinate (Vitamin B₃) 35,0 mg

Inactive ingredients: Colloidal silicone dioxide, hypromellose, magnesium stearate and microcrystalline cellulose.

Sugar free.

Suitable for vegans and vegetarians.

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine

Discipline 34.11 Health Supplement: Vitamins

PHARMACOLOGICAL ACTION

Inositol hexanicotinate consists of six nicotinic acid molecules cross-linked to an inositol molecule. It is an alternative form of vitamin B₃, or niacin, that is known to decrease flushing. Inositol nicotinate has been traditionally used to improve blood circulation. The effects of inositol nicotinate in peripheral vascular disorders such as Raynaud syndrome, suggest that fibrinolysis, lipid lowering, and vasodilatory action contribute to its beneficial effects.

INDICATIONS

SOLAL® FLUSH-FREE NIACIN 35 mg helps to metabolise carbohydrates, fats and proteins. It contributes to the maintenance of normal mucous membranes and normal skin. Assists with normal psychological function and the reduction of tiredness and fatigue. It contributes to normal growth and development. A factor in the maintenance of good health.

CONTRAINDICATIONS

Hypersensitivity (allergy) to any of the ingredients of SOLAL® FLUSH-FREE NIACIN 35 mg.

WARNINGS and SPECIAL PRECAUTIONS

Use SOLAL® FLUSH-FREE NIACIN 35 mg with caution in patients with unstable angina. Inositol nicotinate is metabolized to niacin in the body and niacin causes vasodilation (see **INTERACTIONS**). Patients with bleeding disorders should be advised by a relevant healthcare provider before taking SOLAL® FLUSH-FREE NIACIN 35 mg (see **INTERACTIONS**).

Due to the fibrinolytic effects of inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg), patients should discontinue SOLAL® FLUSH-FREE NIACIN 35 mg at least 2 weeks before elective surgical procedures (see **INTERACTIONS**).

Patients with gallbladder disease should use SOLAL® FLUSH-FREE NIACIN 35 mg with caution (see **INTERACTIONS**).

SOLAL® FLUSH-FREE NIACIN 35 mg should be used with caution in patients with kidney disease (see **INTERACTIONS**). This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

INTERACTIONS

Inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) may increase the risk of bleeding and bruising when used concomitantly with anticoagulant/antiplatelet drugs (such as warfarin, aspirin and clopidogrel).

Theoretically, inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) may cause hyperglycemia, abnormal glucose tolerance, and/or glycosuria and may diminish the effects of antidiabetic drugs (eg, metformin).

Inositol hexanicotinate is metabolized to niacin in the body. Niacin-induced vasodilation and flushing may be related to histamine and/or prostacyclin release.

Inositol hexanicotinate in SOLAL® FLUSH-FREE NIACIN 35 mg is metabolized to niacin in the body and there is concern that niacin might exacerbate active gallbladder disease.

Inositol hexanicotinate is excreted unchanged in the urine and might accumulate in patients with kidney disease.

HUMAN REPRODUCTION

Safely during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults: Take 1 capsule once daily after food.

SIDE EFFECTS

Orally inositol hexanicotinate (as in SOLAL® FLUSH-FREE NIACIN 35 mg) is well tolerated. However, common side effects may include gastrointestinal upset, pain, constipation, diarrhea, flushing, heartburn, liver enzyme elevation, nausea and vomiting.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

IDENTIFICATION

A clear, SOLAL branded (black ink) capsule containing a white powder.

PRESENTATION

A white plastic container with a white plastic screw cap and a seal for protection, containing 60 capsules.

STORAGE INSTRUCTIONS

Store at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Ascendis Consumer Brands (Pty) Ltd

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  A PROUD BRAND OF
SPECIALISTS IN HEALTHY AGEING Ascendis HEALTH