

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

MIST ALBA oral suspension

Magnesium sulphate heptahydrate, light magnesium carbonate.

Preservative: Sodium benzoate 0,5 % *m/v*.

Contains alcohol: 2,4 % *m/v*.

Sugar free.

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.

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

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What MIST ALBA is and what it is used for

MIST ALBA is a health supplement and contains magnesium. It is used as a factor in the maintenance of good health.

2. What you need to know before you take MIST ALBA

Do not take MIST ALBA:

- if you are hypersensitive (allergic) to magnesium sulphate heptahydrate, light magnesium carbonate or any of the other ingredients of MIST ALBA (see **What MIST ALBA contains**).

Warnings and precautions

Take special care with MIST ALBA:

- if you have any kidney problems.

Ensure that you stay properly hydrated if you experience diarrhoea while taking MIST ALBA.

MIST ALBA contains alcohol.

Other medicines and MIST ALBA

Always tell your healthcare 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:

- Tetracycline antibiotics (used to treat bacterial infections); or
- Bisphosphonates (used to treat osteoporosis).

You must take your dose of MIST ALBA 2 hours before, or 4 to 6 hours after taking any of the above medicines.

MIST ALBA with food and drink

See section 3 (**How to take MIST ALBA**).

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 healthcare provider for advice before taking this medicine. Safety and efficacy of MIST ALBA during pregnancy and breastfeeding have not been established. Do not use MIST ALBA if you are pregnant.

Driving and using machines

MIST ALBA is unlikely to have an effect on your ability to drive a vehicle and use machines.

3. How to take MIST ALBA

Do not share your medicines with any other person.

Always take MIST ALBA 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.

The usual dose is:

Children 4 – 8 years of age: 1 ml – 1,5 ml once a day.

Adults and children from 9 years of age: 2 ml – 4 ml once a day.

If you have the impression that the effect of MIST ALBA is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

Shake the bottle well before use.

MIST ALBA can be taken with or without food.

If you take more MIST ALBA than you should

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

Take this leaflet and the rest of the remaining MIST ALBA with you so the doctor will know what you have taken.

4. Possible side effects

MIST ALBA can have side effects.

Not all side effects reported for MIST ALBA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MIST ALBA, please consult your healthcare provider for advice.

If any of the following happens, stop taking MIST ALBA 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 MIST ALBA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- stomach irritation;
- nausea (feeling sick);
- vomiting (being sick);
- diarrhoea.

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 “**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 MIST ALBA.

5. How to store MIST ALBA

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the container tightly closed.
- Do not use after the expiry date printed on the container.
- 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 MIST ALBA contains

Each 1 ml contains:

The active substances are:

Magnesium sulphate heptahydrate	400 mg
Light magnesium carbonate	50 mg
providing a total of magnesium (elemental)	53,25 mg

The other ingredients are aqua menthae piperitae concentrata (containing alcohol, peppermint oil and purified water), purified water, sodium benzoate and xanthan food gum.

Preservative: Sodium benzoate 0,5 % *m/v*.

Contains alcohol: 2,4 % *m/v*.

What MIST ALBA looks like and contents of the pack

A white, peppermint flavoured suspension.

2,5 L amber HDPE jerrycan with white ratchet cap; or

100 ml white HDPE bottle with white snap cap.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd

1 Van Tonder Street

Sunderland Ridge

Centurion

0157

info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

The Professional Information for MIST ALBA is available on <http://www.brunel.co.za/mist-alba-100-ml/> or can be requested from the contact details above.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

MIST ALBA orale suspensie

Magnesiumsulfaatheptahidraat, ligte magnesiumkarbonaat.

Preserveermiddel: Natriumbensoaat 0,5 % *m/v*.

Bevat alkohol: 2,4 % *m/v*.

Suikervry.

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

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

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

MIST ALBA is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet MIST ALBA nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

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

1. Wat is MIST ALBA en waarvoor word dit gebruik

MIST ALBA is 'n gesondheidsaanvulling en bevat magnesium. Dit word gebruik as 'n faktor om goeie gesondheid in stand te hou.

2. Wat jy moet weet voordat jy MIST ALBA neem

Moet nie MIST ALBA neem nie

Indien jy hipersensitief (allergies) is vir magnesiumsulfaatheptahidraat, ligte magnesiumkarbonaat of vir enige van die ander bestanddele van MIST ALBA (sien **Wat MIST ALBA bevat**).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met MIST ALBA

- Indien jy enige nierprobleme het.

Maak seker dat jy behoorlik gehidreer bly indien jy diarree ondervind terwyl jy MIST ALBA neem. MIST ALBA bevat alkohol.

Ander medisyne en MIST ALBA

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

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- Tetrasiklienantibiotika (gebruik om bakteriële infeksies te behandel); of
- Bisfosfonate (gebruik om osteoporose te behandel).

Jy moet jou dosis MIST ALBA neem 2 uur voor, of 4 tot 6 uur nadat jy enige van bogenoemde medisyne geneem het.

MIST ALBA met kos en drinkgoed

Sien afdeling 3.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy MIST ALBA neem.

Dit is nie vasgestel of MIST ALBA veilig en effektief tydens swangerskap en borsvoeding is nie. Moet nie MIST ALBA gebruik indien jy swanger is nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat MIST ALBA 'n uitwerking op jou vermoë om 'n voertuig te bestuur en masjiene te gebruik sal hê.

3. Hoe om MIST ALBA te neem

Moet nie jou medisyne met enigiemand anders deel nie.

Skud deeglik voor gebruik.

Die gebruikelike dosis is:

Kinders 4 – 8 jaar: 1 ml – 1,5 ml een keer per dag.

Volwassenes en kinders vanaf 9-jarige ouderdom: 2 ml – 4 ml een keer per dag.

Moet nie die aanbevole dosis oorskry nie. Neem MIST ALBA altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou aangewys het. Vra gerus jou dokter of apteker indien jy onseker is.

MIST ALBA kan met of sonder kos geneem word.

Indien jy die indruk kry dat die uitwerking van MIST ALBA te sterk of te swak is, bespreek dit met jou dokter of apteker.

Indien jy meer MIST ALBA geneem het as wat jy moet

In geval van oordosering, konsulteer jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die houer met die oorblywende MIST ALBA saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike newe-effekte

MIST ALBA kan newe-effekte hê.

Nie alle newe-effekte wat vir MIST ALBA gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy MIST ALBA neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om MIST ALBA 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 newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op MIST ALBA gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

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

Newe-effekte wat minder dikwels voorkom:

- maagirritasie;
- naarheid;
- braking;
- diarree.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reactions Reporting Form**”, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van MIST ALBA te verskaf.

5. Hoe om MIST ALBA te bêre

- Bêre teen of onder 25 °C.
- Hou dig toe.
- Bêre alle medisyne buite bereik van kinders.
- Moet nie gebruik na die vervaldatum wat op die houer gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat MIST ALBA bevat

Elke 1 ml bevat:

Magnesiumsulfaatheptahidraat	400 mg
Ligte magnesiumkarbonaat	50 mg
lewer 'n totaal van magnesium (elementaal)	53,25 mg

Die ander bestanddele is aqua menthae piperitae concentrata (wat alkohol, pepermentolie en gesuiwerde water bevat), gesuiwerde water, natriumbensoaat en xantaangom.

Hoe MIST ALBA lyk en inhoud van die verpakking

'n Wit, pepermentgeur suspensie.

2,5 L amber HDPE-kan met 'n wit ratelprop; of

100 ml wit HDPE-bottel met 'n wit aanknip-proppie.

HOUER VAN DIE REGISTRASIESERTIFIKAAT

Brunel Laboratoria (Edms.) Bpk.

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA aangedui word.

REGISTRASIENOMMER

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir MIST ALBA is beskikbaar by <http://www.brunel.co.za/mist-alba-100-ml/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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