

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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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

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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.