Patient information leaflet for NEUTRACID SUSPENSION

SCHEDULING STATUS: S0

NEUTRACID SUSPENSION

Dried aluminium hydroxide gel

Magnesium hydroxide

Simeticone

Contains sugar (700 mg sorbitol and 0,55 mg sucrose per 5 mL).

Contains sweetener (5 mg saccharin sodium per 5 mL).

Preservatives: 0,2 % *m/v* methyl hydroxybenzoate and 0,02 % *m/v* propyl hydroxybenzoate.

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

- NEUTRACID SUSPENSION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use NEUTRACID SUSPENSION carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share NEUTRACID SUSPENSION with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What NEUTRACID SUSPENSION is and what it is used for

NEUTRACID SUSPENSION contains the active substances dried aluminium hydroxide gel, magnesium hydroxide and simeticone. Dried aluminium hydroxide gel and magnesium hydroxide are antacids, while simeticone is an anti-foaming medicine.

NEUTRACID SUSPENSION is used for the relief of:

- Gas (excessive wind) associated with acid indigestion.
- Excessive stomach acid.
- Heartburn, indigestion and acid reflux.
- Symptoms associated with inflammation of your stomach.
- Symptoms associated with ulcers (sores) in your stomach.

NEUTRACID SUSPENSION works by lowering the amount of acid and removing gas in your stomach.

2. What you need to know before you take NEUTRACID SUSPENSION

Do not take NEUTRACID SUSPENSION:

If you are allergic (hypersensitive) to dried aluminium hydroxide gel, magnesium hydroxide, simeticone or any of the other ingredients of NEUTRACID SUSPENSION listed in section 6 of this leaflet.

Warnings and precautions

Take special care with NEUTRACID SUSPENSION:

- If you have kidney problems. Ask your health care provider for advice before using NEUTRACID SUSPENSION.
- If you are on a low-phosphorus diet.
- If you are 65 years or older.
- If you have porphyria and are undergoing kidney dialysis.
- If you are taking any antibiotic medicines (used to treat bacterial infections).

Tell your doctor or health care provider if you experience any of the following symptoms of increased magnesium levels in the body:

- nausea (feeling sick) or vomiting (being sick);
- diarrhoea;
- flushing of your skin;
- feeling tired;
- feeling confused;
- increased thirst;
- a loss of reflexes;
- breathing slower than usual;
- muscle weakness;
- changes in the way your heart beats.

Children and adolescents

The safety and efficacy of NEUTRACID SUSPENSION in children have not yet been established.

Other medicines and NEUTRACID SUSPENSION

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

NEUTRACID SUSPENSION should not be taken at the same time as other medicines. Take NEUTRACID SUSPENSION at least one hour before or after taking any other medicine.

NEUTRACID SUSPENSION may reduce the uptake of the following medicines into the blood, which may reduce their effectiveness:

- Tetracyclines, ciprofloxacin or cefpodoxime (used to treat bacterial infections).
- Vitamins (supplements).
- Ketoconazole (used to treat fungal infections).
- Chloroquine (used to prevent and treat malaria or to treat rheumatoid arthritis).

- Rifampicin (used to treat tuberculosis [TB]).
- Chlorpromazine (used to treat psychosis).
- Levothyroxine (used to treat an underactive thyroid).
- Rosuvastatin (used to lower cholesterol).
- Polystyrene sulphonate (used to lower potassium levels).

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 NEUTRACID SUSPENSION.

Driving and using machines

It is not known whether NEUTRACID SUSPENSION may impair your ability to drive a vehicle or use machinery. Do not drive a vehicle or operate machinery until you know how NEUTRACID SUSPENSION affects you.

NEUTRACID SUSPENSION contains sorbitol

NEUTRACID SUSPENSION contains 700 mg sorbitol per 5 mL. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take NEUTRACID SUSPENSION.

NEUTRACID SUSPENSION contains sucrose

NEUTRACID SUSPENSION contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NEUTRACID SUSPENSION.

NEUTRACID SUSPENSION contains preservatives

NEUTRACID SUSPENSION contains methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions and exceptionally, bronchospasm.

NEUTRACID SUSPENSION contains carmoisine

NEUTRACID SUSPENSION contains carmoisine as a colourant which may cause allergic reactions.

3. How to take NEUTRACID SUSPENSION

Always take NEUTRACID SUSPENSION exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Shake the bottle before use.

The usual dose is 10 mL to 20 mL (2 to 4 medicine measures) three times daily, taken 20 minutes after meals, and at bedtime, or as directed by your doctor.

Do not take more than 80 mL (16 medicine measures) in a 24-hour period.

Do not use the maximum dose of NEUTRACID SUSPENSION for more than 2 weeks, except under the advice or supervision of your doctor.

If you take more NEUTRACID SUSPENSION 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 NEUTRACID SUSPENSION bottle with any remaining NEUTRACID SUSPENSION with you, so that your doctor or nurse knows what you have taken.

4. Possible side effects

NEUTRACID SUSPENSION can have side effects.

Not all side effects reported for NEUTRACID SUSPENSION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NEUTRACID SUSPENSION, please consult your health care provider for advice.

If any of the following happens, stop NEUTRACID SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and 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 reaction to NEUTRACID SUSPENSION. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- too high levels of magnesium in your blood (thirst, low blood pressure, drowsiness, confusion, muscle weakness, difficulty breathing, irregular heartbeat, coma, death);
- diarrhoea, nausea (feeling sick), vomiting (being sick), constipation.

Side effects occurring with an unknown frequency:

- pain in the stomach area;
- too low levels of phosphate in your body (muscle weakness, feeling tired, bone pain, loss of appetite, confusion, irritability, bone fractures);
- bowel obstruction (blockage);
- hyperaluminaemia (an electrolyte disturbance in which there is an abnormally elevated level of aluminium in the body).

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 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 NEUTRACID SUSPENSION.

5. How to store NEUTRACID SUSPENSION

- Store at or below 30 °C.
- Keep the container tightly closed until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the bottle.
- 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 NEUTRACID SUSPENSION contains

The active substances in NEUTRACID SUSPENSION are dried aluminium hydroxide gel, magnesium hydroxide and simeticone.

Each 5 mL contains:	
Dried aluminium hydroxide gel	200 mg
Magnesium hydroxide	159,2 mg
Simeticone	25 mg

The other ingredients in NEUTRACID SUSPENSION are hypromellose, methyl hydroxybenzoate, peppermint oil (flavourant), propyl hydroxybenzoate, purified water, raspberry red H1227 (colourant, containing carmoisine and sucrose), saccharin sodium, sodium hypochlorite, sorbitol and triacetin.

What NEUTRACID SUSPENSION looks like and contents of the pack

Pink, peppermint flavoured suspension, with no visible contaminants.

200 mL white round HDPE bottle with a polypropylene screw cap with or without a measuring cup,

placed in an outer carton.

Pack size: 200 mL

OR

200 mL type II round amber glass bottle with a polypropylene screw cap with or without a measuring cup, placed in an outer carton.

Pack size: 200 mL.

Holder of certificate of Registration

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Access to corresponding Professional Information

Request via the email address: info@lebasi.co.za