PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

UNIENZYME coated tablets

Activated charcoal / Papain / Nicotinamide (Vitamin B3) / Alpha amylase

Contains sugar (50 mg lactose monohydrate and 91 mg sucrose per tablet).

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

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

UNIENZYME is available without a doctor's prescription for you to treat a mild illness.

Nevertheless, you still need to take UNIENZYME carefully to get the best results from it.

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

1. What UNIENZYME is and what it is used for

UNIENZYME can be used as a digestive aid and to assist with the relief of digestive problems such as indigestion, bloating, burping and flatulence (wind).

2. What you need to know before you take UNIENZYME

Do not take UNIENZYME:

If you are hypersensitive (allergic) to activated charcoal, papain, vitamin B3, alpha amylase or any of the other ingredients of UNIENZYME (listed in section 6).

Warnings and precautions

Take special care with UNIENZYME if you have a known allergy to latex or fruit (such as avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach and tomato).
UNIENZYME contains papain and may cause an allergic reaction if you have a known latex or fruit allergy.

Consult a relevant health care provider before taking UNIENZYME:

- if you have diabetes;
- if you have malabsorption or other gastrointestinal problems;
- if you are going to have an operation;
- if you are pregnant or breastfeeding;
- for use beyond four (4) weeks.

Consult a relevant health care provider if symptoms develop, worsen or persist.

Children and adolescents

UNIENZYME is not suitable for children under 18 years of age.

Other medicines and UNIENZYME

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

UNIENZYME contains activated charcoal and may interact with other medicines.

Consult your doctor, pharmacist or relevant health care provider before taking UNIENZYME if you are currently using:

- blood thinners;
- antibiotic medicines (used to treat bacterial infections);
- anti-inflammatory medicines.

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 UNIENZYME.

Safety during pregnancy and breastfeeding has not been established.

Driving and using machines

UNIENZYME has no effect on the ability to drive a vehicle and use machines.

UNIENZYME contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking UNIENZYME.

3. How to take UNIENZYME

Do not share medicines with any other person.

Always take UNIENZYME 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:

One (1) tablet daily.

A maximum daily dose of six (6) tablets should not be exceeded. UNIENZYME should be taken

with a meal unless otherwise instructed by a relevant health care provider.

You should swallow the tablet whole; do not crush or chew the tablet.

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

If you take more UNIENZYME than you should

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

Take this leaflet and the remaining UNIENZYME tablets with you so the doctor will know what you have taken.

4. Possible side effects

UNIENZYME can have side effects.

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

If any of the following happens, stop taking UNIENZYME 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 reaction to UNIENZYME. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- pain in your stomach area;
- constipation;
- nausea (feeling sick), vomiting (being sick);
- diarrhoea.

Side effects with an unknown frequency:

- black discolouration of your tongue and the inside of your mouth;
- black stools.

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 UNIENZYME.

5. How to store UNIENZYME

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- 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 UNIENZYME contains

Each coated tablet contains:

Activated charcoal	75 mg
Papain	30 mg*
Nicotinamide (Vitamin B3)	25 mg
Alpha amylase	20 mg**

*Papain enzymatic activity: 180 000 FCC PU.

**Alpha amylase enzymatic activity: 76 – 90 FCC DU.

The other ingredients are acacia, calcium carbonate, carmellose sodium, carnauba wax, castor oil, colloidal anhydrous silica, edible white ink, gelatine, lactose monohydrate, magnesium stearate, microcrystalline cellulose, purified talc, shellac, simeticone, sodium benzoate 0,025 % *m/m* (preservative), sucrose and vegetable charcoal.

What UNIENZYME looks like and contents of the pack

Black, oval-shaped, sugar-coated tablets with “UNICHEM” printed in white on one side.

Silver aluminium blister strips containing 10 tablets.

Pack size: 10, 30 or 100 tablets.*

* Not all these pack sizes may be marketed.

Holder of certificate of registration

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7551

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This leaflet was last revised in

September 2025.

Registration number

Will be allocated by SAHPRA upon registration.