Professional Information for UNIENZYME

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

UNIENZYME coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.

Excipients with known effect:

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

Contains preservative (sodium benzoate 0,025 % *m/m*).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablets.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

UNIENZYME can be used for symptomatic relief in digestive disorders manifested by bloating, belching, flatulence, abdominal discomfort or the feeling of abdominal fullness. It will also assist in the proper digestion of basic nutrients such as carbohydrates, proteins and fats.

4.2 Posology and method of administration

Take 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.

Paediatric population

Not suitable for children under 18 years of age.

4.3 Contraindications

Hypersensitivity to activated charcoal, alpha amylase, papain, vitamin B3 or to any of the excipients of UNIENZYME (listed in section 6.1).

4.4 Special warnings and precautions for use

Fruit allergies

Caution is advised in patients with 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 in patients with known fruit allergies.

A relevant health care provider should be consulted:

- if symptoms develop, worsen or persist;
- if a patient has diabetes;

- if a patient is having surgery;
- before use if a patient is pregnant or breastfeeding;
- for use beyond four (4) weeks.

UNIENZYME should be used with caution in individuals with malabsorption conditions since it may interfere with absorption of nutrients (see section 4.5). A relevant health care provide should be consulted before use if a patient has malabsorption or other gastrointestinal ailments.

Sugar warning

UNIENZYME contains sugar (sucrose and lactose). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, sucrase-isomaltase insufficiency, galactose intolerance or total lactase deficiency, should not take UNIENZYME.

4.5 Interaction with other medicines and other forms of interaction

UNIENZYME contains activated charcoal and may interact with other medicines.

Blood thinners, antibiotic medicines and anti-inflammatory medicines

A relevant health care provider should be consulted before use if a patient is taking blood thinners, antibiotic medicines or anti-inflammatory medicines.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Immune system disorders

Less frequent: Hypersensitivity reactions.

Gastrointestinal disorders

Less frequent: Abdominal pain, constipation, nausea, vomiting, diarrhoea.

Frequency unknown: Black discolouration of tongue and mucous membranes, black faeces.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of UNIENZYME is important. It allows continued monitoring of the benefit/risk balance of UNIENZYME. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.12 Multiple substance formulation

Mechanism of action

UNIENZYME contains a combination of ingredients which assist in digestive disorders and with the digestion of basic nutrients.

Pharmacodynamic effects

Activated charcoal has adsorbing properties and has been shown to adsorb gases.

Alpha amylase is a digestive enzyme that occurs naturally in the body.

Papain is a digestive enzyme found in the papaya fruit.

Vitamin B3 is a water-soluble vitamin that helps the body to metabolise carbohydrates, proteins and fats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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 (preservative)

Sucrose

Vegetable charcoal.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the blister strips in the outer carton until required for use.

6.5 Nature and contents of container

Silver aluminium blister strips containing 10 tablets.

Pack size: 10, 30 or 100 tablets.*

* Not all these pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unichem SA (Pty) Ltd

San Domenico, Ground Floor, Unit 4

10 Church Street, Durbanville

Cape Town

7551

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

September 2025.