



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

CATALYST PREGNANCY WITH QUATREFOLIC® ACID tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

QUATREFOLIC® (5-Methyltetrahydrofolic acid)	953 µg
providing 500 µg folate equivalent to folic acid	300 µg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

White tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CATALYST PREGNANCY WITH QUATREFOLIC® ACID can contribute to maternal tissue growth during pregnancy and help to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy. Quatrefolic® is a 4th generation folate that can assist with homocysteine regulation, cardiovascular and cognitive support.

4.2 Posology and method of administration

Women: Take 1 tablet daily.

The tablet should be taken with or after a meal.

Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to folic acid or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

CATALYST PREGNANCY WITH QUATREFOLIC® ACID can be taken during pregnancy and lactation. Supplementing with folic acid as contained in CATALYST PREGNANCY WITH QUATREFOLIC® ACID while planning to fall pregnant and during pregnancy (especially in the first 12 weeks) is recommended, since it may reduce the risk of neural tube defects (see section 4.1).

4.7 Effects on ability to drive and use machines

CATALYST PREGNANCY WITH QUATREFOLIC® ACID is unlikely to affect the ability to drive a vehicle and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of CATALYST PREGNANCY WITH QUATREFOLIC® ACID are known.

4.8 Undesirable effects

None known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of CATALYST PREGNANCY WITH QUATREFOLIC® ACID is important. It allows continued monitoring of the benefit/risk balance of CATALYST PREGNANCY WITH QUATREFOLIC® ACID. Health care providers are asked to report any suspected adverse reactions 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>

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 34.11 Vitamins.

Mechanism of action:

Folic acid is a water-soluble B₉ vitamin. Folic acid helps with the formation of red blood cells and contributes to maternal tissue growth during pregnancy. It also helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate

Microcrystalline cellulose (E460(i)).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

6.5 Nature and contents of container

175 mL amber PET jars with white flip top lids with a white shrink sleeve.

Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6

10 Church Street

Durbanville 7550

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

October 2020.