

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

FOLIC ACID FORTE (Tablets)

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each FOLIC ACID FORTE tablet contains:

Ingredient	Per tablet
Vitamin C (Ascorbic acid)	200 mg
Vitamin B6 (Pyridoxine hydrochloride)	24 mg
Vitamin B3 (Nicotinamide)	18 mg
Vitamin B5 (Calcium d-pantothenate)	15 mg
Calcium (Calcium d-pantothenate)	1,58 mg
Vitamin B2 (Riboflavin)	5 mg
Vitamin B1 (Thiamine mononitrate)	3 mg
Folic acid (Folic acid)	500 µg
Vitamin B12 (Cyanocobalamin)	24 µg

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Oval shaped, pink, film coated tablet.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

FOLIC ACID FORTE is a health supplement containing folic acid, b-vitamins and vitamin C for the maintenance of good health.

#### 4.2 Posology and method of administration

##### Adults and children 14 years and older:

Take one tablet daily before food, or as directed by a healthcare provider.

#### 4.3 Contraindications

Not for use in patients who are hypersensitive to any of the ingredients, including excipients.

#### 4.4 Special warnings and precautions for use

Use in children below the age of 14 years is at the discretion of a healthcare professional.

#### 4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on FOLIC ACID FORTE. The following are noted in the monographs of the active ingredients:

Folic acid may interfere with the action of anti-cancer medicines such as methotrexate and anticonvulsants such as phenytoin/phenobarbital.

#### 4.6 Fertility, pregnancy and lactation

FOLIC ACID FORTE is suitable for use during pregnancy and lactation at the recommended dose.

#### 4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

#### 4.8 Undesirable effects

Possible side effects are:

- gastrointestinal discomfort (nausea, vomiting, abdominal pain, diarrhoea, constipation)
- skin rash

#### 4.9 Overdose

Symptoms of overdosage include vomiting, diarrhoea, abdominal cramps, flatulence and a bitter taste in the mouth. Treatment is symptomatic and supportive.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement  
D34.12 Multiple substance formulation

### 5.2 PHARMACOLOGICAL ACTION

- Folic Acid contributes to maternal tissue growth during pregnancy and helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy.
- The B Vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin, regulation of hormonal activity, normal function of the heart, and the reduction of tiredness and fatigue.
- Vitamin C is an antioxidant for the maintenance of good health. It contributes to cell protection from free radical damage, helps in the development and maintenance of bones, cartilage, teeth and gums and helps with connective tissue formation.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Absolute ethanol, dibasic calcium phosphate, colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, povidone, purified talc, sodium starch glycolate. Coating: Opadry pink. Sugar free.

### 6.2 Incompatibilities

Unknown

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store at or below 25 °C. Protect from sunlight and moisture.  
KEEP OUT OF THE REACH OF CHILDREN.

### 6.5 Nature and contents of container

Blister packs of 10 tablets each, packed in cartons of 30 and 60 tablets.

### 6.6 Special precautions for disposal and other handling

No special requirements

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

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## 8 REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

## 9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020