FLORA FORCE® SLIPPERY ELM Tablets

Western herbal medicine
This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:
Not Scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):
FLORA FORCE® SLIPPERY ELM Tablets

COMPOSITION:
Each **FLORA FORCE® SLIPPERY ELM** tablet contains:

ACTIVE INGREDIENT	QUANTITY
Ulmus rubra bark powder	500 mg

Inactive ingredients: Lactose, gum acacia and magnesium stearate.
FLORA FORCE® SLIPPERY ELM tablets are free from sugar.

PHARMACOLOGICAL CLASSIFICATION:
D 11.10, Gastro-intestinal tract, Other.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
The slippery elm inner bark rind contains mucilage which is considered the principal active constituents. The mucilage is thought to be responsible for slippery elm's demulcent and emollient effects. Also, used internally, slippery elm may cause reflex stimulation of nerve ending in the GI tract, leading to mucous secretions. This induced mucous may protect the GI tract.

INDICATIONS:
FLORA FORCE® SLIPPERY ELM tablets aid with the relief of symptoms associated with indigestion.

CONTRA-INDICATIONS:
None known.

WARNINGS AND SPECIAL PRECAUTIONS:
When starting or stopping treatment with **FLORA FORCE® SLIPPERY ELM** tablets, patients taking other oral medications should be monitored (see "**INTERACTIONS**").

The use of **FLORA FORCE® SLIPPERY ELM** tablets in children and adolescents under 18 years of age is not recommended due to lack of adequate data (see "**DOSAGE AND DIRECTIONS FOR USE**").

Effects on the ability to drive or use machinery:
No studies on the effect of **FLORA FORCE® SLIPPERY ELM** tablets on the ability to drive or operate machines have been performed. It is unlikely that **FLORA FORCE® SLIPPERY ELM** tablets will affect the ability to drive or operate machines.

INTERACTIONS:
Ulmus rubra bark, as in **FLORA FORCE® SLIPPERY ELM** tablets may interact with other oral medications. Theoretically, slippery elm may slow the absorption, and reduce levels of orally administered drugs, due to its mucilage content. Patients taking **FLORA FORCE® SLIPPERY ELM** should be monitored and the dose of medications may need to be adjusted when taken in conjunction with **FLORA FORCE® SLIPPERY ELM** tablets (see "**WARNINGS AND SPECIAL PRECAUTIONS**")**.**

PREGNANCY AND LACTATION:
The safety and efficacy of **FLORA FORCE® SLIPPERY ELM** tablets during pregnancy and lactation have not been established. Tablets should therefore not be taken during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:
The recommended daily dose should not be exceeded.

Adults (18 years and older):
Take 1-2 tablets 3 times daily with meals or as prescribed. Take with a glass of water.

Children (under 18 years of age):
Not recommended for use (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

SIDE-EFFECS:
None known.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:
None known. Contact a poison control centre in area.

IDENTIFICATION:
12mm biconvex round caramel coloured herbal tablet

PRESENTATION:
30 tablets in a 75ml amber glass bottle or 90 tablets packed in a 125ml amber glass bottle with a seal and dark green cap in a box.

STORAGE INSTRUCTIONS:
Store at or below 25 ºC in a dry place.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Flora Force Heath Products (Pty) Ltd.
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