SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ZCOUGH 100 mg soft capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains: Benzonatate 100mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft capsule

ZCOUGH 100 mg soft capsule:
Round shape and clear light yellow soft capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ZCOUGH is indicated for the symptomatic relief of cough.

4.2 Posology and method of administration

Pharmacology
ZCOUGH Soft Capsules 100mg is a non-narcotic oral antitussive agent.
ZCOUGH Soft Capsules 100mg acts peripherally by anesthetizing the stretch receptors located in the respiratory passages, lungs, and stretch receptor on pleura by dampening their activity and thereby reducing the cough reflex at its source. It begins to act within 15 to 20 minutes and its effect for 3 to 8 hours. It has no inhibitory effect on the respiratory center in recommended dosage.

Dosage and Administration

Adults: 1 – 2 capsules three times a day.
Swallow the pill whole.

4.3 Contraindications

Hypersensitivity to benzonatate or related compounds.

4.4 Special warnings and precautions for use

Warnings and Precautions
- Children below age 14 and those who have difficulty swallowing should not use.
- Active ingredient release from the capsule in the mouth can produce a temporary local anesthesia of the oral mucosa and choking could occur. Swallow whole. Do not chew.
- Nursing mothers: It is not known whether this drug is excreted in human milk. Close attention when administer.
- Carcinogenicity, mutagenicity and reproduction studies have not been conducted.

Toxic Symptoms
If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly, which may cause choking and airway compromise. Further central inhibition may lead to clonic spasm.

Toxic Treatment

- Evacuate gastric contents and administer copious amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials.
- Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage.
- Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication.
- Do not use CNS stimulants

Hypersensitivity

Severe hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or chewing the capsule instead of swallowing it. Severe reactions have required intervention with vasopressor agents and supportive measures.

Psychiatric Effects

Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking ZCOUGH in combination with other prescribed drugs.

Accidental Ingestion and Death in Children

Keep ZCOUGH out of reach of children. Accidental ingestion of ZCOUGH resulting in death has been reported in children below age 10. Signs and symptoms of overdose have been reported within 15-20 minutes and death has been reported within one hour of ingestion. If accidental ingestion occurs, seek medical attention immediately (see OVERDOSAGE).

PRECAUTIONS

Benzonatate is chemically related to anesthetic agents of the para-amino-benzoic acid class (e.g. procaine; tetracaine) and has been associated with adverse CNS effects possibly related to a prior sensitivity to related agents or interaction with concomitant medication.

4.5 Interaction with other medicinal products and other forms of interaction

Benzonatate is chemically related to anesthetic agents of the para-amino-benzoic acid class (e.g. procaine; tetracaine) and has been associated with adverse CNS effects possibly related to a prior sensitivity to related agents or interaction with concomitant medication.

4.6 Pregnancy and lactation

It should be given to a pregnant woman only if clearly needed. (Animal reproduction studies have not been conducted.)

4.7 Effects on ability to drive and use machines

There is limited information on the effects on ability to drive and use machines.

4.8 Undesirable effects

Sedation, headache, slight dizziness, itching, rash, stuffy nose, constipation, nausea, gastrointestinal upset, burning eyes, fear of cold, chest pain, allergies have been reported.

General

The most serious side effects reported were bronchospasm, laryngospasm, and cardiovascular collapse.

Hypersensitivity

Frequency not reported: Bronchospasm, laryngospasm, cardiovascular collapse, hypersensitivity

Nervous system

Frequency not reported: Sedation, headache, dizziness, mental confusion, visual hallucinations.

Respiratory

Frequency not reported: Nasal congestion, numbness of the chest

Gastrointestinal

Frequency not reported: Constipation, nausea, GI upset

Dermatologic

Frequency not reported: Pruritus, skin eruptions

Ocular

Frequency not reported: Sensation of burning in the eyes

Other

Frequency not reported: Vague "chilly" sensation

4.9 Overdose

Intentional and unintentional overdose may result in death, particularly in children.
The drug is chemically related to tetracaine and other topical anesthetics and shares various aspects of their pharmacology and toxicology. Drugs of this type are generally well absorbed after ingestion.

Signs and Symptoms:
The signs and symptoms of overdose of benzonatate have been reported within 15-20 minutes. If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly, which may cause choking and airway compromise.

CNS stimulation may cause restlessness and tremors which may proceed to clonic convulsions followed by profound CNS depression. Convulsions, coma, cerebral edema and cardiac arrest leading to death have been reported within 1 hour of ingestion.

Treatment:
In case of overdose, seek medical attention immediately. Evacuate gastric contents and administer copious amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials. Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage. Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication from overdosage.

Do not use CNS stimulants.

5. PHARMACOLOGICAL PROPERTIES

See section 4.2 Pharmacology.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule shell:
Gelatin 160
Glycerin
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30℃. Keep out of reach of children.

6.5 Nature and contents of container

The finished product is packed in HDPE bottles with PP cap, 500 counts per bottle with one desiccant.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Alvogen (Thailand) Limited, Bangkok, Thailand.

Manufactured by
Lotus Pharmaceutical Co., Ltd., No.30, Chenggong 1st Rd., Sinsing Village, Nantou City, Taiwan.

8. MARKETING AUTHORISATION NUMBER(S)

Reg. No.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}
<Date of latest renewal: {DD month YYYY}>

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}