ULTAK 150 / 300

SCHEDULING STATUS:

S3

PROPRIETARY NAME (AND DOSAGE FORM):

ULTAK-150 mg (Tablets)

ULTAK-300 mg (Tablets)

COMPOSITION:

ULTAK-150 mg tablets:

Each tablet contains:

Ranitidine	150 mg (as the hydrochloride).

ULTAK-300 mg tablets:

Each tablet contains:

Ranitidine	300 mg (as the hydrochloride).

PHARMACOLOGICAL CLASSIFICATION:

Category A.11.4.3 Medicines acting on gastro-intestinal tract. Antacids-other.

PHARMACOLOGICAL ACTION:

ULTAK is a selective H_2 receptor antagonist that competitively inhibits the interaction of histamine with the H_2 receptors. Due to its specificity, it has little or no effect on the H_1 and other receptors, it does not exhibit antiserotonergic activity, nor does **ULTAK** show any measurable affinity for androgen, oestrogen, progesterone, glucocorticoid or mineralocorticoid receptors, and does not affect serum prolactin concentrations.

ULTAK inhibits in a dose dependent manner, basal (fasting) and nocturnal acid secretions stimulated by food and other physiological vagal reflexes, reducing both the volume of gastric acid secretions and its acid (H^+) concentration. The pepsin output falls proportionally with the reduction in volume of gastric juice, and does not affect the gastric mucous secretion.

ULTAK is readily absorbed from the gastro-intestinal tract and is subject to first-pass hepatic metabolism. The major metabolites are the N-oxide with smaller quantities of S-oxide and desmethyl ranitidine. Peak plasma concentrations are reached within 2 – 3 hours after oral administration. The elimination half-life of ranitidine is 2 – 3 hours. Absorption is not impaired by food.

ULTAK does not interact with cytochrome P450-linked drug metabolizing enzyme systems.

INDICATIONS:

ULTAK is indicated for the treatment of: duodenal ulcers, benign gastric ulcers including the prevention of duodenal ulceration associated with non-steroidal anti-inflammatory agents, Zollinger-Ellison syndrome, and reflux oesophagitis. **ULTAK** may also be used in patients at risk of developing acid aspiration syndrome during general anaesthesia.

CONTRA-INDICATIONS

Hypersensitivity to ranitidine hydrochloride.

Also contra-indicated in patients suffering from porphyria, or history of acute porphyria.

Ranitidine **(ULTAK)** crosses the placenta, is also distributed into breast milk and its safety in pregnancy and lactation has not been established.

ULTAK should be avoided in patients with a history of porphyria.

DOSAGE AND DIRECTIONS FOR USE:

Do not take antacid preparations within 0.5 – 1 hour of taking **ULTAK**, as this may limit the absorption of **ULTAK**.

Duodenal and gastric ulcers:

A single dose of 300 mg taken at bedtime or 150 mg taken twice daily in the morning and at bedtime is recommended, given initially for 4 – 8 weeks. The dose may be increased up to a maximum of 300 mg twice daily.

A maintenance dose of 150 mg once daily may be given at bedtime.

Healing may occur in 4 weeks. Ulcers that do not heal within 4 weeks may require further course of treatment.

Maintenance therapy:

For patients with a history of recurrent peptic ulcers, responsive to short-term therapy, an extended low dose maintenance treatment of **ULTAK** 150 mg at bedtime, is recommended.

It is not necessary to time the dose administration in relation to mealtimes.

Reflux Oesophagitis:

150 mg twice daily or 300 mg at bedtime for up to 8 – 12 weeks.

Zollinger-Ellison syndrome:

Starting dose: 150 mg two – three times daily, increased as necessary up to 600 mg – 900 mg per day in divided doses.

In Anaesthesia:

300 mg given at least 2 hours before anaesthesia is indicated to reduce the consequences of the acid aspiration syndrome.

Alternatively 150 mg may be given 12 hours prior, followed by a further 150 mg 2 hours prior to anaesthesia, to effectively suppress gastric secretion.

NON-STEROIDAL ANTI-INFLAMMATORY TREATMENT:

In ulcers following non-steroidal anti-inflammatory therapy or associated with continued non-steroidal anti-inflammatory agents, treatment may be necessary for 8 to 12 weeks. For the prevention of duodenal ulcers associated with non-steroidal anti-inflammatory (NSAI) treatment, **ULTAK** 150 mg twice daily may be given concomitantly with the NSAI therapy.

Children:

Experience with the use of ranitidine in children is limited.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Headache, tiredness and dizziness have been reported. Cases of reversible mental confusion, depression and hallucinations have been reported, especially, in the elderly and the severely ill patient.

Constipation, diarrhoea, nausea and vomiting have also been reported.

Skin rash including cases suggestive of erythema multiforme have been reported.

Transient and reversible changes in liver function tests may occur. Hepatitis (hepatocanicular, hepatocellular or mixed) with or without jaundice, have occasionally been reported. These are usually reversible.

Blood count change (leucopenia or thrombocytopenia) have been reported.

Cases of agranulocytosis, neutropenia or of pancytopenia, sometimes with marrow hypoplasia or aplasia have been reported.

Anaphylactoid reactions such as urticaria, fever, bronchospasm, hypotension, angio-neurotic oedema and anaphylactic shock, have been reported. These reactions may occur after a single dose.

There have been reports of bradycardia and AV block following the administration of **ULTAK**.

Cases of acute pancreatitis, arthralgia and myalgia may occur.

No clinically significant interference with endocrine or gonadal function has been reported. There have been reports of breast symptoms (discomfort, pain and/or swelling) and gynaecomastia in men.

Special Precautions:

Treatment with H_2 antagonists may mask symptoms associated with carcinoma of the stomach. This may therefore delay the diagnosis of the condition. The possibility of malignancy should therefore be excluded before therapy with **ULTAK** is started.

Due to **ULTAK** renal excretion pathway, increased plasma levels will be experienced in patients with renal impairment, and a dose reduction to 150 mg daily is recommended.

Periodic examinations should be carried out on patients on prolonged maintenance treatment to safeguard against the occurrence of unforeseeable consequences of the treatment.

Caution is recommended in patients with cardiovascular disease.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See side-effects. Symptomatic and supportive therapy should be given. The medicine may be removed by haemodialysis, if the need arises.

IDENTIFICATION:

ULTAK-150: White to Off-white circular biconvex tablets, plain on both sides.

ULTAK-300: White to Off-white capsule shaped tablets, with a breakline on the one side.

PRESENTATION:

Cartons of 30 or 60 strip packed tablets.

STORAGE INSTRUCTIONS:

Store in a tight light resistant container, in a dry place, below 30°C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

ULTAK-150: Reg no: 32/11.4.3/0539

ULTAK-300: Reg no: 32/11.4.3/0540

NAME AND BUSINESS ADDRESS OF APPLICANT:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

April 2000.

[1] Change in HCR/FPRR (Refer to 1.7.9 – Letters of cession and acceptance)
[2] Change in address (Refer to 1.7.9 – Letters of cession and acceptance)