# SUMMARY OF PRODUCT CHARACTERISTICS

**1. Name of the Medicinal Product**

**GENERIC NAME:** Ranitidine Tablets BP 150 mg

**BRAND NAME:** RANIKANT 150

**2. QUALITY AND QUANTITATIVE COMPOSITION**

Each film coated tablet contains:

Ranitidine Hydrochloride BP

equivalent to Ranitidine……..150 mg

Excipients…….. q.s.

Colour: Titanium Dioxide & Sunset Yellow FCF

For complete list of excipients refer section 6.1

**3. Pharmaceutical Form**

Solid, Oral dosage form- Tablets

Orange coloured, circular biconvex, film coated tablet, plain on both sides.

**4. Clinical Particulars**

**4.1 Therapeutic Indications**

Duodenal ulcer; benign gastric ulcer, reflux oesophagitis; postoperative gastric ulceration and other hyperacidity syndromes where reduction of acidity is beneficial.

**4.2 Posology and method of administration**

As directed by physician.

**4.3 Contraindications**

Hypersensitivity to Ranitidine.

**4.4 Special warning and precaution for use**

Exclude the presence of gastric malignancy.

Concomitant use of NSAID especially in elderly and in those with history of peptic ulcer.Dose to be adjusted in patients with renal impairment.

**4.5 Interaction with other medicinal products and other forms of interaction**

Antacids may interfere with absorption.

**4.6 Pregnancy and lactation**

Pregnancy: Use only if clearly indicated.

Lactation: The drug passes into breast milk.At normal doses adverse effects on the baby are unlikely.

**4.7 Effects on ability to drive and use machine**

None reported.

**4.8 Undesirable effects**

The following have been reported as events in clinical trials or in the routine management of patients treated with ranitidine. The relationship to ranitidine therapy has not been established in many cases.

Transient and reversible changes in liver function tests can occur. There have been occasional reports of hepatitis (hepatocellular, hepatocanalicular or mixed)with or without jaundice. These were usually reversible. Acute pancreatitis has been reported rarely.

Leucopenia and thrombocytopenia have occurred rarely in patients. These are usually reversible. Rare cases of agranulocytosis or of pancytopenia, sometimes with marrow hypoplasmia, or aplasia have been reported.

Hypersensitivity reactions (urticaria, angioneurotic oedema, fever, bronchospasm, hypotension, anaphylactic shock) have been seen rarely following the parenteral and oral administration of ranitidine. These reactions have occasionally occurred after a single dose.

As with other H2-receptor antagonists ,there have been rare reports of bradycardia and A-V block and asystole.

Headache ,some time severe and dizziness have been reported in very small proportion of patients. Rare cases of reversible mental confusion, depression and hallucinations have been reported, predominately in severely ill and elderly patients. In addition, reversible involuntary movement disorders have been reported rarely.

Skin rash has been reported, including rare cases of erythema multiforme. Musculoskeletal symptoms such as arthralgia and myalgia have been reported rarely. Rare cases of vasculitis and alopecia.

Reversible impotence has been reported rarely.

No clinically significant interference with endocrine or gonadal function has been reported. There have been a few reports of breasts symptoms (swelling and/or discomfort) in men taking ranitidine; some cases have resolved on continued ranitidine treatment.

Discontinuation of therapy may be necessary in order to establish the underlying cause.

Antibiotic associated diarrhoea may occur when amoxicillin and metronidazole are taken with ranitidine.

**4.9 Overdose**

**Symptoms and Signs**

Ranitidine is very specific in action and no particular problems are expected following overdosage with ranitidine formulations.

**Treatment**

Symptomatic and supportive therapy should be given as appropriate.

**5.0 Pharmacological properties**

**5.1 Pharmacodynamic Properties**

ATC Code: A02B A02 - Drugs for peptic ulcers and gastro-oesophageal reflux disease (GORD); H2-receptor antagonists

Ranitidine is a specific, rapidly acting histamine H2-antagonist.

Ranitidine inhibits basal and stimulated secretion of gastric acid, reducing both the volume and the acid and pepsin content of the secretion. Ranitidine has a relatively long duration of action and so a single 150mg dose effectively suppresses gastric acid secretion for 12 hours.

## 5.2 Pharmacokinetics

### Absorption

Following oral administration of 150 mg ranitidine, maximum plasma concentrations (300 to 550 ng/mL) occurred after 1—3 hours. Two distinct peaks or plateau in the absorption phase result from reabsorption of drug excreted into the intestine. The absolute bioavailability of ranitidine is 50-60% and plasma concentrations increase proportionally with increasing dose up to 300 mg.

### Distribution

Ranitidine is not extensively bound to plasma proteins (15%), but exhibits a large volume of distribution ranging from 96 to 142 L.

### Metabolism

Ranitidine is not extensively metabolised. The fraction of the dose recovered as metabolites is similar after both oral and i.v. dosing; and includes 6% of the dose in urine as the N-oxide, 2% as the S-oxide, 2% as desmethylranitidine and 1 to 2% as the furoic acid analogue.

### Elimination

Plasma concentrations decline bi-exponentially, with a terminal half-life of 2-3 hours. The major route of elimination is renal. After IV administration of 150 mg 3H-ranitidine, 98% of the dose was recovered, including 5% in faeces and 93% in urine, of which 70% was unchanged parent drug. After oral administration of 150 mg 3H-ranitidine, 96% of the dose was recovered, 26% in faeces and 70% in urine of which 35% was unchanged parent drug. Less than 3% of the dose is excreted in bile. Renal clearance is approximately 500 mL/min, which exceeds glomerular filtration indicating net renal tubular secretion.

### Special Patient Populations

Children (3 years and above)

Limited pharmacokinetic data have shown that there are no significant differences in half-life (range for children 3 years and above: 1.7 - 2.2 h) and plasma clearance (range for children 3 years and above: 9 - 22ml/min/kg) between children and healthy adults receiving oral ranitidine when correction is made for body weight.

**Patients over 50 years of age**

In patients over 50 years of age, half-life is prolonged (3-4 h) and clearance is reduced, consistent with the age-related decline of renal function. However, systemic exposure and accumulation are 50% higher. This difference exceeds the effect of declining renal function, and indicates increased bioavailability in older patients.

**5.3 Preclinical Safety Data**

No additional data of relevance.

## 6. PHARMACEUTICAL PARTICULARS

**6.1 List of Excipients**

Microcrystalline Cellulose, Dibasic calcium Phosphate Dihydrate , Maize Starch , Methyl Hydroxybenzoate, Propyl Hydroxybenzoate , Povidone K30 ,Purified Talc , Magnesium Stearate, Sodium Starch Glycolate ,Colloidal anhydrous silica, Instamoist shield A21D00328-Orange

**6.2 Incompatibilities**

Not Applicable

**6.3 Shelf Life**

36 months.

**6.4 Special Precaution for Storage-**

Store below 30°C, in a dry place. Protect from light.

Keep the medicine out of reach of children.

**6.5 Nature and Contents of Container-**

Alu-Alu strip of 10 tablets

**7. MARKETING AUTHORISATION HOLDER:**

S Kant Healthcare Limited.

3-A Shiv Sagar Estate, North Wing,

Dr. Annie Besant Road, Worli,

Mumbai-400 018 (India)

Phone: 91-22-6622 7575

Fax: 91-22-6622 7500/6622 7600

E-mail: www.sk1932.com

**8. NATIONAL REGISTRATION NUMBER**

08439/REN/2022

**9. DATE OF AUTHORISATION**

21-06-2022

**10. DATE OF REVISION OF THE TEXT**

July 2023