For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory Only

RANITIN

1. Generic Name:

Ranitidine hydrochloride Tablets I.P.

2. Qualitative and quantitative composition:

RANITIN-150

Each film coated tablet contains:

Ranitidine Hydrochloride I.P.

Equivalent to ranitidine…..…..150 mg

Colour: Titanium dioxide I.P.

RANITIN-300

Each film coated tablet contains:

Ranitidine Hydrochloride I.P.

Equivalent to ranitidine……300 mg

Colour: Titanium dioxide I.P.

The excipients are Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Idealaqua.

3. Dosage form and strength:

Dosage form: Film coated tablet

Strength: Ranitidine Hydrochloride 150/300 mg

4. Clinical particulars:

4.1 Therapeutic indication:

Ranitidine Hydrochloride Indicated in the treatment of duodenal ulcer, benign gastric ulcer, post-operative ulcer, reflux oesophagitis, Zollinger Ellison syndrome.

4.2 Posology and method of administration:

Posology

Adults (including the elderly):

The usual dosage is 150 mg twice daily, taken in the morning and evening. Patients with duodenal ulceration, gastric ulceration or oesophageal reflux disease may be treated with a single bedtime dose of 300 mg. It is not necessary to time the dose in relation to meals.

Duodenal ulcer, benign gastric ulcer and post-operative ulcer:

In most cases of duodenal ulcer, benign gastric ulcer and post-operative ulcer, healing occurs in four weeks. Healing usually occurs after a further four weeks of treatment in those patients whose ulcers have not fully healed after the initial course of therapy.

NSAID associated peptic ulceration, including prophylaxis of duodenal ulcers:

In ulcers following non-steroidal anti-inflammatory drug therapy or associated with continued non-steroidal anti-inflammatory drugs, eight weeks treatment may benecessary.

In duodenal ulcer 300 mg twice daily for 4 weeks results in healing rates which are higher than those at 4 weeks with ranitidine 150 mg twice daily or 300 mg nocte. The increased dose has not been associated with an increased incidence of unwanted effects.

Duodenal ulcers associated with Helicobacter pylori infection:

For duodenal ulcers associated with Helicobacter pylori infection ranitidine 300 mg at bedtime or 150 mg twice daily may be given with oral amoxicillin 750 mg three times daily and metronidazole 500 mg three times daily for two weeks. Therapy with ranitidine should continue for a further 2 weeks. This dose regimen significantly reduces the frequency of duodenal ulcer recurrence.

Maintenance treatment at a reduced dosage of 150 mg at bedtime is recommended for patients who have responded to short-term therapy, particularly those with a history of recurrent ulcer.

Oesophageal reflux disease:

In the management of oesophageal reflux disease, the recommended course of treatment is either 150 mg twice daily or 300 mg at bedtime for up to 8 weeks or if necessary 12 weeks.

In patients with moderate to severe oesophagitis, the dosage of ranitidine may be increased to 150 mg 4 times daily for up to 12 weeks.

***Zollinger-Ellison syndrome*:**

In patients with Zollinger-Ellison syndrome, the starting dose is 150 mg three times daily and this may be increased as necessary. Patients with this syndrome have been given increasing doses up to 6 g per day and these doses have been well tolerated.

***Chronic episodic dyspepsia*:**

For patients with chronic episodic dyspepsia the recommended course of treatment is 150 mg twice daily for up to six weeks. Anyone not responding or relapsing shortly afterwards should be investigated.

In the prophylaxis of haemorrhage from stress ulceration in seriously ill patients or the prophylaxis of recurrent haemorrhage in patients bleeding from peptic ulceration, treatment with Ranitin Tablets 150 mg twice daily may be substituted for Ranitin Injection (see separate SPC) once oral feeding commences in patients considered to be still at risk from these conditions.

Prophylaxis of acid aspiration (Mendleson's syndrome):

In patients thought to be at risk of acid aspiration syndrome an oral dose of 150 mg can be given 2 hours before induction of general anaesthesia, and preferably also 150 mg the previous evening.

In obstetric patients at commencement of labour, an oral dose of 150 mg may be given followed by 150 mg at six hourly intervals. It is recommended that since gastric emptying and drug absorption are delayed during labour, any patient requiring emergency general anaesthesia should be given, in addition, a non-particulate antacid (e.g. sodium citrate) prior to induction of anaesthesia. The usual precautions to avoid acid aspiration should also be taken.

Children 12 years and over:

For children 12 years and over the adult dosage is given.

Children from 3 to 11 years and over 30 kg of weight

See section 5.3 Pharmacokinetic properties (Other special populations)

Patients over 50 years of age:

See section 5.3 Pharmacokinetic properties (Other special Populations)

Peptic Ulcer Acute Treatment:

The recommended oral dose for treatment of peptic ulcer in children is 4 mg/kg/day to 8 mg/kg/day administered as two divided doses to a maximum of 300 mg ranitidine per day for a duration of 4 weeks. For those patients with incomplete healing, another 4 weeks of therapy is indicated, as healing usually occurs after eight weeks of treatment.

Gastro-Oesophageal Reflux:

The recommended oral dose for the treatment of gastro-oesophageal reflux in children is 5 mg/kg/day to 10 mg/kg/day administered as two divided doses to a maximum of 600 mg (the maximum dose is likely to apply to heavier children or adolescents with severe symptoms).

Neonates:

Safety and efficacy in new-born patients has not been established.

Patients with renal impairment:

Accumulation of ranitidine with resulting elevated plasma concentrations will occur in patients with renal impairment (creatinine clearance less than 50 ml/min). Accordingly, it is recommended that the daily dose of ranitidine in such patients should be 150 mg at night for 4-8 weeks. The same dose should be used for maintenance treatment, if necessary. If an ulcer has not healed after treatment, 150 mg twice daily dosage should be instituted followed, if need be, by maintenance treatment of 150 mg at night.

Method of administration:

For oral administration.

4.3 Contraindication:

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use:

Malignancy

The possibility of malignancy should be excluded before commencement of therapy in patients with gastric ulcer and in patients of middle age and over with new or recently changed dyspeptic symptoms) as treatment with ranitidine may mask symptoms of gastric carcinoma.

Renal Disease

Ranitidine is excreted via the kidney and so plasma levels of the drug are increased in patients with renal impairment.

Regular supervision of patients who are taking non-steroidal anti-inflammatory drugs concomitantly with ranitidine is recommended, especially in the elderly. Current evidence

shows that ranitidine protects against NSAID associated ulceration in the duodenum and not in the stomach.

Rare clinical reports suggest that ranitidine may precipitate acute porphyric attacks. Ranitidine should therefore be avoided in patients with a history of acute porphyria.

In patients such as the elderly, persons with chronic lung disease, diabetes or the immunocompromised, there may be an increased risk of developing community acquired pneumonia. A large epidemiological study showed an increased risk of developing community acquired pneumonia in current users of ranitidine alone versus those who had stopped treatment, with an observed adjusted relative risk increase of 1.82 (95% CI 1.26-2.64). Post-marketing data indicate reversible mental confusion, depression, and hallucinations have been reported most frequently in severely ill and elderly patients.

Important information about excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

4.5 Drug-Interaction:

Ranitidine has the potential to affect the absorption, metabolism or renal excretion of other drugs. The altered pharmacokinetics may necessitate dosage adjustment of the affected drug or discontinuation of treatment.

Interactions occur by several mechanisms including:

1) Inhibition of cytochrome P450-linked mixed function oxygenase system:

Ranitidine at usual therapeutic doses does not potentiate the actions of drugs which are inactivated by this enzyme system such as diazepam, lidocaine, phenytoin, propanolol and theophylline. There have been reports of altered prothrombin time with coumarin anticoagulants (e.g. warfarin). Due to the narrow therapeutic index, close monitoring of increased or decreased prothrombin time is recommended during concurrent treatment with ranitidine.

2) Competition for renal tubular secretion:

Since ranitidine is partially eliminated by the cationic system, it may affect the clearance of other drugs eliminated by this route. High doses of ranitidine (e.g. such as those used in the treatment of Zollinger-Ellison syndrome) may reduce the excretion of procainamide and N-acetylprocainamide resulting in increased plasma level of these drugs.

3) Alteration of gastric pH:

The bioavailability of certain drugs may be affected. This can result in either an increase in absorption (e.g. triazolam, midazolam, glipizide) or a decrease in absorption (e.g. ketoconazole, atazanavir, delaviridine, gefitnib).

Concomitant administration of 300 mg ranitidine and erlotinib decreased erlotinib exposure [AUC] and maximum concentrations [Cmax] by 33% and 54%, respectively. However, when erlotinib was dosed in a staggered manner 2 hours before or 10 hours after ranitidine 150 mg b.i.d., erlotinib exposure [AUC] and maximum concentrations [Cmax] decreased only by 15% and 17%, respectively.

There is no evidence of an interaction between ranitidine and amoxicillin or metronidazole.

If high doses (2 g) of sucralfate are co-administered with ranitidine the absorption of the latter may be reduced. This effect is not seen if sucralfate is taken after an interval of 2 hours.

4.6 Use in special populations:

Pregnancy

Ranitidine crosses the placenta but therapeutic doses administered to obstetric patients in labour or undergoing caesarean section have been without any adverse effect on labour, delivery or subsequent neonatal progress. Like other drugs, ranitidine should only be used during pregnancy if considered essential.

Breast-feeding

Ranitidine is excreted in human breast milk. Like other drugs, ranitidine should only be used during breast-feeding if considered essential.

Fertility

There are no data on the effects of ranitidine on human fertility. There were no effects on male and female fertility in animal studies.

4.7 Effects on ability to drive and use machines:

None reported.

4.8 Undesirable effects:

The following convention has been utilised for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, ≤1/100), rare (≥1/10,000, ≤1/1000), very rare (≤1/10,000). Adverse event frequencies have been estimated from spontaneous reports from post-marketing data.

Blood & Lymphatic System Disorders

Very Rare: Blood count changes (leucopenia, thrombocytopenia). These are usually reversible. Agranulocytosis or pancytopenia, sometimes with marrow hypoplasia or marrow aplasia.

Immune System Disorders

Rare: Hypersensitivity reactions (urticaria, angioneurotic oedema, fever, bronchospasm, hypotension and chest pain).

Very Rare: Anaphylactic shock.

Not known: Dyspnoea.

These events have been reported after a single dose.

Psychiatric Disorders

Very Rare: Reversible mental confusion, depression and hallucinations.

These have been reported predominantly in severely ill patients, in elderly and in nephropatic patients.

Nervous System Disorders

Very Rare: Headache (sometimes severe), dizziness. and reversible involuntary movement disorders.

Eye Disorders

Very Rare: Reversible blurred vision.

There have been reports of blurred vision, which is suggestive of a change in accommodation.

Cardiac Disorders

Very Rare: As with other H2 receptor antagonists bradycardia, A-V block, cardiac arrest and tachycardia.

Vascular Disorders

Very Rare: Vasculitis**.**

Gastrointestinal Disorders

Uncommon: Abdominal pain, constipation, nausea (these symptoms mostly improved during continued treatment).

Very Rare: Acute pancreatitis, diarrhoea

Hepatobiliary Disorders

Rare: Transient and reversible changes in liver function tests.

Very Rare: Hepatitis (hepatocellular, hepatocanalicular or mixed) with or without jaundice, these were usually reversible.

Skin and Subcutaneous Tissue Disorders

Rare: Skin Rash.

Very Rare: Erythema multiforme, alopecia**.**

Musculoskeletal and Connective Tissue Disorders

Very Rare: Musculoskeletal symptoms such as arthralgia and myalgia.

Renal and Urinary Disorders

Rare: Elevation of plasma creatinine (usually slight; normalised during continued treatment)

Very Rare: Acute interstitial nephritis.

Reproductive System and Breast Disorders

Very Rare: Reversible impotence, breast symptoms and breast conditions (such as gynaecomastia and galactorrhoea).

Paediatric population

The safety of ranitidine has been assessed in children ages 0 to 16 years with acid-related disease and was generally well tolerated with an adverse event profile resembling that in adults. There are limited long term data available, in particular regarding growth and development**.**

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose:

Symptoms and signs

Ranitidine is very specific in action and accordingly no particular problems are expected following overdosage.

Treatment

Symptomatic and supportive therapy should be given as appropriate.

5. Pharmacological properties:

5.1 Mechanism of Action:

Pharmacotherapeutic group: H2-receptor antagonists

ATC code: A02BA02

Ranitidine is a specific rapidly acting histamine H2-antagonist. It 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 150 mg dose effectively suppresses gastric acid secretion for twelve hours.

5.2 Pharmacodynamic properties:

In studies with therapeutic doses of 150 mg twice daily, ranitidine decreased gastric acid secretion by 63% and 69%, respectively, over 24 hours, with nocturnal acid secretion reduction being 73% and 90%, respectively. Ranitidine led to a reduction in gastric acid secretion of 42% and 69% within 24 hours respectively, in the relapse prophylaxis (150 mg at night).

At therapeutic doses of 300 mg ranitidine at night, gastric acid secretion was reduced by an average of 50-60% within 24 hours, reducing nocturnal acid secretion by nearly 90%**.**

5.3 Pharmacokinetic properties:

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 a 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.

Other special 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 - 22 ml/min/kg) between children and healthy adults receiving oral ranitidine when correction is made for body weight.

Patients over 50 years of age

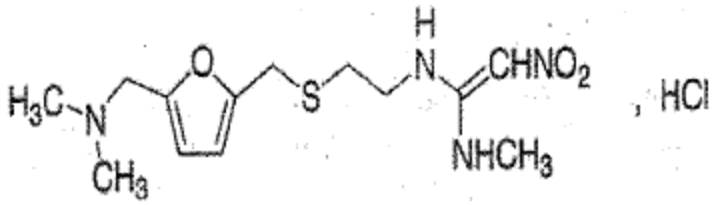
In patients over 50 years of age, half-life is prolonged (3-4 h) and clearance is reduced, consistent with the age-related decline of renal function. However, systemic exposure and accumulation are 50% higher. This difference exceeds the effect of declining renal function, and indicates increased bioavailability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

6. Nonclinical properties:

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

7. Description:

Ranitidine Hydrochloride is N-2-[[[5-(dimethylamino}methyl] furan-2-yl]methyl]thio]ethyl]-N-methyl-2-nitroethene-1,1-diamine hydrochloride having molecular formula of C13H22N4O3S●HCl molecular weight is 350.9 the chemical structure is:



Ranitidine is a white to pale yellow, crystalline powder.

Product Description:

RANITIN-150:

White to off white coloured, round, biconvex, film coated tablet debossed with "RANITIN 150" on one side and plain on other side.

RANITIN-300:

White to off white coloured, round, biconvex, film coated tablet debossed with "RANITIN 300" on one side and plain on other side.

8. Pharmaceutical particulars:

8.1 Incompatibilities:

Not applicable.

8.2 Shelf-life:

Do not use later than the date of expiry.

8.3 Packaging information:

RANITIN-150

Available in blister of 40 Tablets

RANITIN-300

Available in blister of 10 Tablets

8.4 Storage and handing instructions:

Keep in a cool dry place, protected from light.

Keep out of reach of Children.

9. Patient Counselling Information

Package leaflet: Information for the user

RANITIN

Ranitidine hydrochloride Tablets I.P.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1. What RANITIN is and what it is used for

RANITIN contains a medicine called ranitidine. This belongs to a group of medicines called H_2-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) RANITIN is used to:

- heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- help clear up infection in your stomach, when taken with antibiotic medicines (medicines taken to treat germs)
- stop stomach ulcers when they are a side effect of some medicines

- stop ulcers from bleeding
- improve problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as ‘indigestion’, ‘dyspepsia’ or ‘heartburn’
- stop acid coming up from the stomach while under anaesthetic during an operation.

For children (3 to 18 years) RANITIN is used to:

- heal ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- heal and stop problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as ’indigestion’, ’dyspepsia’ or ’heartburn’.

9.2. What you need to know before you take RANITIN

Do not take RANITIN if:

- you are allergic to ranitidine or any of the other ingredients of this medicine.

If you are not sure, talk to your doctor or pharmacist before taking RANITIN.

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine if:

- you have stomach cancer
- you have kidney problems. You will need to take a different amount of RANITIN
- you have had stomach ulcers before and you are taking Non-Steroidal antiInflammatory (NSAID) medicines
- you have a rare condition called acute porphyria
- you are over 65 years old
- you have lung disease
- you are diabetic
- you have any problems with your immune system.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and RANITIN

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because RANITIN can affect the way some other medicines work. Also, some other medicines can affect the way RANITIN works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Non-Steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation
- lidocaine, a local anaesthetic
- propranolol, procainamide or n-acetylprocainamide, for heart problems
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy
- theophylline, for breathing problems (asthma)
- warfarin, for thinning your blood.
- glipizide, for lowering blood glucose
- atazanavir or delavirdine, for treating HIV infection
- triazolam, for insomnia

- gefitinib, for lung cancer
- ketoconazole, an anti fungal medicine, sometimes used for treating thrush
- erlotinib; for certain types of cancer
- sucralfate, for treating stomach ulcers.

Midazolam is a medicine that may be given to you just before you have an operation.

Tell the doctor you are taking RANITIN before your operation in case he or she wants to give you midazolam.

If you are taking erlotinib, a drug used for the treatment of certain types of cancer, talk to your doctor before you take RANITIN Tablet. Ranitidine contained in RANITIN Tablet may decrease the amount of erlotinib in your blood and your doctor may need to adjust your treatment if it is used while you are receiving erlotinib.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before taking RANITIN.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. You should not take this medicine unless your doctor advises it is essential.

Important information about the contents of RANITIN Tablets

300mg Tablets:

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

9.3. How to take RANITIN

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow each tablet whole with a glass of water.

The usual dose for an adult (including the elderly) is either:

- 150 mg in the morning and 150 mg in the evening, or
- 300 mg at bedtime.

Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Use in children 12 years and over:

The adult dose is given.

Use in children over 30 kg of weight and from 3 to 11 years:

Your doctor will work out the right dose for you based on your child's weight.

Treatment of stomach or duodenal (small intestine) ulcers:

The usual dose is 2 mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 4 mg for each kg, twice a day. Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

Treatment of heartburn due to too much acid:

The usual dose is 2.5 mg for each kg of body weight, twice a day for two weeks. This dose may be increased to 5 mg for each kg, twice a day. Take each dose about 12 hours apart.

If you take more RANITIN than you should

RANITIN is not normally harmful if you take more than you should, unless you take many tablets at once. If this applies to you (or someone else taking this medicine), **you should go to your nearest hospital casualty department straight away.**

Take the medicine pack or any remaining medicine with you so that the doctor knows what you have taken.

If you forget to take RANITIN

- If you forget a dose, take it as soon as you remember it, unless it is nearly time for your next dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking RANITIN

After a few days of taking the tablets you should start to feel much better. Do not stop taking the tablets without talking to your doctor or pharmacist first, otherwise the original pain and discomfort may come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

9.4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine.

Stop taking RANITIN and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reactions, the signs may include:
  - rash, itching or hives on the skin
  - swelling of your face, lips, tongue or other parts of the body
  - chest pain, shortness of breath, wheezing or having trouble breathing
  - unexplained fever and feeling faint, especially when standing up
- kidney problems, which can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood tests
- severe stomach pain, this may be a sign of something called ‘pancreatitis’
- a slow or irregular heartbeat

Check with your doctor at your next visit if you notice any of the following:

Uncommon (may affect up to 1 in 100 people)

- stomach pain
- constipation
- feeling sick (nausea)

Rare (may affect up to 1 in 1,000 people)

- skin rash

Rare side effects that may show up in blood tests:

- increase of serum creatinine in the blood (kidney function test)
- changes to liver function

Check with your doctor as soon as possible if you notice any of the following:

Very rare (may affect up to 1 in 10,000 people)

- there can be changes in the level of certain substances in your blood. This can lead to you feeling unusually tired or short of breath and being more likely to bruise or get an infection
- feeling depressed, confused, seeing or hearing unexplained things (hallucinations)
- headache (sometimes severe)
- feeling dizzy or having blurred vision
- your joints or muscles are painful or swollen or you cannot control their movement
- your small blood vessels can become swollen (known as 'vasculitis'). Signs of this can include: a rash, swollen joints or kidney problems
- your liver can become swollen. This can lead to: nausea (feeling sick) or vomiting (being sick), loss of appetite or generally feeling unwell, itching, fever, yellowing of the skin and eyes or dark coloured urine
- flushing or marks on your skin that look like targets
- unexplained hair loss
- diarrhoea
- impotence
- breast tenderness and/or breast enlargement
- breast discharge
- awareness of the heart beat and/or increased heart rate

Not known (frequency cannot be estimated from the available data)

- shortness of breath

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

9.5. How to store RANITIN

Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.
- Keep in a cool dry place, protected from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

9.6. Contents of the pack and other information

What Ranitin contains:

The active substance is Ranitidine Hydrochloride.

RANITIN-150

Available in blister of 40 Tablets

Colour: Titanium dioxide I.P.

RANITIN-300

The excipients are Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Idealaqua.

Available in blister of 10 Tablets

What Ranitin looks like and contents of the pack

RANITIN-150:

White to off white coloured, round, biconvex, film coated tablet debossed with "RANITIN 150" on one side and plain on other side.

RANITIN-300:

White to off white coloured, round, biconvex, film coated tablet debossed with "RANITIN 300" on one side and plain on other side.

10. Details of manufacturer

Torrent Pharmaceutical Ltd

32 No. Middle Camp, NH-10,

East District, Gangtok, Sikkim-737 135.

OR

Torrent Pharmaceutical Ltd (Unit-II)

Plot No. : 725 & 726, 32 No. Middle Camp, NH-10, East District, Gangtok, Sikkim-737 135

OR

Biogenetic Drugs Pvt. Ltd.

Jharmazri, Baddi, Dist. Solan (H.P.) – 174103

RANITIN-300

Torrent Pharmaceutical Ltd

32 No. Middle Camp, NH-10,

East District, Gangtok, Sikkim-737 135.

OR

Biogenetic Drugs Pvt. Ltd.

Jharmazri, Baddi, Dist. Solan (H.P.) - 174103

11. Details of permission or licence number with date

RANITIN-150

Torrent Pharmaceutical Ltd

Mfg. Lic no. M/563/2010 issued on 25.09.2012

OR

Torrent Pharmaceutical Ltd (Unit-II)

Mfg. Lic no. M/785/2017

OR

Biogenetic Drugs Pvt. Ltd.

Mfg. Lic no. MNB/05/150 issued on 25.02.2021

RANITIN-300

Torrent Pharmaceutical Ltd

Mfg. Lic no. M/563/2010 issued on 25.09.2012

OR

Biogenetic Drugs Pvt. Ltd.

Mfg. Lic no. MNB/05/150 issued on 25.02.2021

12. Date of revision

FEB 2022

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/RANITIN 150,300 mg/FEB-22/04/PI