Ulcerex® Tablets / Injection / Suspension
(Cimetidine)

COMPOSITION:
Ulcerex® 400mg Tablets:
Each film coated tablet contains:
Cimetidine USP……400mg

Ulcerex® Injection:
Each 2ml contains:
Cimetidine USP……200mg
For intramuscular injection or slow intravenous injection or intravenous infusion

Ulcerex® Suspension:
Each 5ml contains:
Cimetidine USP……200mg

INDICATION:
Ulcerex® is a H2 – receptor antagonist which rapidly inhibits both basal and stimulated gastric secretion of acid and reduces pepsin output. **Ulcerex®** is indicated in the treatment of duodenal and benign gastric ulceration including that associated with non-steroidal anti-inflammatory agents, recurrent and stomach ulceration, esophageal reflux disease and other conditions where reduction of gastric acid by **Ulcerex®** has been shown to be beneficial: Persistent dyspeptic symptoms, with or without ulceration, particularly meal-related upper abdominal pain, including such symptoms associated with non-steroidal, anti-inflammatory agents; the prophylaxis of gastro-intestinal haemorrhage in seriously ill patients, before general anesthesia in patients thought to be at risk of acid aspiration, particularly obstetric patients during labour to reduce malabsorption and fluid loss in the short bowel syndrome; and in pancreatic insufficiency to reduce degradation of enzyme supplements

DOSAGE AND ADMINISTRATION:
The total daily dose by any means route should not normally exceed 2.4gm
Dosage should be reduced in patients with impaired renal function

Tablet:
Adults:
For patients with duodenal or benign gastric ulceration, single daily dose of 800mg at bedtime usual dosage is 400mg twice a day with breakfast and at bedtime. Others include 200mg three times daily with meals and 400mg at bedtime and if inadequate, 400mg four times a day also with meals and at bedtime
Treatment may be continued for longer periods in those patients who may benefit from reduction of gastric secretion and the dosage may be reduced as appropriate to 400mg at bedtime or 400mg in the morning
In patients with benign peptic ulcer disease, relapse may be prevented by continued treatment, usually 400mg at bed time or 400mg in the morning has also been used
In esophageal reflux disease, 400mg four times a day, with meals and at bedtime, for 4 - 8 weeks is recommended to heal esophagitis and relieve associated symptoms
In patients with very high gastric acid secretion (e.g. Zollinger-Ellison syndrome) it may be necessary to increase the dose to 400mg four times a day or in occasional cases further. For stress ulceration, doses of 200 – 400mg can be given every 4 - 6 hours by oral, nasogastric or parenteral routes. By direct intravenous injection a dose of 200mg should not be exceeded
In patients thought to be at risk of acid aspiration syndrome an oral dose of 400mg can be given 90 – 120 minutes before induction of general anesthesia or in obstetric practice, at the start labour. While such a risk persists, a dose of up to 400mg may be repeated (parenterally if appropriate) at four-hourly intervals as required up to the usual daily maximum of 2.4g
The usual precautions to avoid acid aspiration should be taken. In short, bowel syndrome, e.g. following substantial resection for crohn's disease, the usual dosage range (see above) can be used according to individual response.
To reduce degradation of pancreatic enzyme supplements, 800 – 1600mg a day may be given according to response in four divided doses, one to one and a half hours before meals

OR
As directed by the physician

Injection:
Ulcerex® may be given intramuscularly or intravenously. The dose by intramuscular injection is normally 200mg which may be repeated at 4 – 6 hours intervals
The usual dosage for intravenous administration is 200 - 400mg which may be repeated 4 – 6 hours intervals
If direct intravenous injection cannot be avoided, 200mg should be given slowly over a period of not less than 5 minutes and may be repeated 4 - 6 hours. Rapid intravenous injection has been associated with cardiac arrhythmias.
If there is a cardiovascular impairment or if a larger dose is needed, the dose should be diluted and given over at least 10 minutes. In such cases infusion is preferable
For intermittent intravenous infusion, the contents of one **Ulcerex®** Infusion bag (containing Cimetidine 400mg in 100ml 0.9% w/v sodium chloride) should be infused over 30 minutes to 1 hour and may be repeated every 4 – 6 hours
If continuous intravenous infusion is required. **Ulcerex®** may be given at an average rate of 50 to 100mg/hour over 24 hours

Elderly: The normal adult dosage may be used unless renal function is markedly impaired

Children: Experience in children is less than that in adults. In children more than one year old, **Ulcerex®** 25 - 30mg/kg body weight per day in divided doses may be administered by either the oral or the parenteral route
The use of **Ulcerex®** in infants under one year old is not fully evaluated; 20mg/kg body weight per day in divided doses has been used

Suspension:
Adults: 1 teaspoonful twice daily
Children: 20 to 40mg per kg body weight daily in divided doses
Dosage can be adjusted according to the condition of individual patients

OR
As directed by the physician

CONTRAINDICATION:
Hypersensitivity to Cimetidine

PRECAUTIONS:
Dosage should be reduced in patients with impaired renal function according to creatinine clearance. The following dosages are suggested: Creatinine clearance of 0 - 15ml per minute, 200mg twice a day; 15 - 30ml per minute, 200mg three times a day; 30 - 50ml per minute, 200mg four times a day; over 50ml per minute, normal dosage. Circulating Cimetidine levels are reduced by hemodialysis and Cimetidine should be administered after dialysis treatment, but levels are unchanged by peritoneal dialysis
Ulcerex® can prolong the elimination of drugs metabolized by oxidation in the liver. Reduction of dose required when using anticoagulants or phenytoin is recommended. Rapid intravenous injection of Cimetidine (less than 5 minutes) should be avoided. Care should be taken that patients with a history of peptic ulcer, particularly the elderly, being treated with **Ulcerex**® and a non-steroidal anti-inflammatory agent are observed regularly. In patients on drug treatment or with illnesses that could cause falls in blood cell count, the possibility that H2-receptor antagonism could potentiate this effect should be borne in mind
Interaction with other medications:
Although pharmacological interactions with a number of drugs e.g. diazepam, propranolol have been demonstrated, only those with warfarin type anticoagulants, phenytoin, theophylline and intravenous lignocaine appear, to date, to be of clinical significance
Pregnancy and Lactation:
There has been limited experience to date with the use of **Ulcerex**® in pregnant patients. Adequate human data on use in lactation are not available. Although tests in animals and clinical evidence have not revealed any hazards from the administration of **Ulcerex**® during pregnancy or lactation, both animal and human studies have shown that it does cross the placental barrier and is excreted in milk. As with most drugs, the use of **Ulcerex**® should be avoided during pregnancy and lactation unless essential

ADVERSE REACTIONS:
Diarrhoea, dizziness, usually mild and transient and tiredness have been reported. Skin rashes, sometimes severe have been observed. Gynaecomastia has been reported and is almost always reversible on discontinuing treatment. Biochemical or biopsy evidence of reversible liver damage such as increases in plasma creatinine, serum transaminase levels and rare cases of hepatitis have been reported occasionally. Reversible confusional states have occurred, usually in elderly or already very ill patients, e.g. those with renal failure. Thrombocytopenia and leucopenia, including agranulocytosis, reversible on withdrawal of treatment, have been reported very rarely. There have been very rare reports of interstitial nephritis, acute pancreatitis, fever, headache, myalgia, sinus bradycardia, tachycardia, heart block and hypersensitivity vasculitis, all reversible on withdrawal of treatment. Rare anaphylaxis and alopecia have been reported. Reversible impotence but no causal relationship has been established at usual therapeutic doses

OVER DOSAGE:
Acute overdosage of up to 20gm has been reported several times with no significant ill effects. Induction of vomiting and/or gastric lavage may be employed together with symptomatic and supportive therapy

STABILITY:
See expiry on the pack

PRESENTATIONS:
Ulcerex® **400mg Tablets** in a pack of 10's
Ulcerex® **Injection** in a pack of 5's
Ulcerex® **Suspension** in a pack of 60ml

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light, humidity and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains undissolved particle(s)

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

السی ریکس ٹیبلٹ/انجکشن/سسپینشن
(سائمیٹڈین)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی
تنبیہ: انجکشن کے لیک ہونے، دھندلا ہونے یا اس میں کوئی غیر حل پزیر
شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں