SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the finished pharmaceutical product

Cimetidine injection USP 200mg/mL

2. Qualitative and quantitative composition for excipients

The composition of Cimetidine injection is shown as the table below:

Ingredients	Quantitative/Unit dosage (in mg)	Specifications (in Kg)	Function
Cimetidine	400.0	20.0	Active ingredient
Hydrochloride acid	--	--	Acidifying agent
Medicinal charcoal*	0.2mg	10g	Adsorbent
Water for injection	q.s	q.s	Diluent

Note: Medicinal charcoal powder will be removed by filtration during production process.

3. Pharmaceutical form

Injection

4. Clinical particulars

4.1 Therapeutic indications

Cimetidine is used to treat ulcers of the stomach or intestines and prevent them from returning after treatment. This medication is also used to treat certain stomach and throat problems caused by too much acid(e.g., Zollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus. (gastroesophageal reflux disease-GERD) This form of cimetidine is given by injection and is used for short term treatment of these conditions when you cannot take this medication by mouth. Your doctor should switch you to taking this medication by mouth when possible. Cimetidine injection is also used to prevent serious stomach bleeding in very ill patients (usually in the hospital/ICU). Cimetidine is known as an H2 histamine blocker. It works by reducing the amount of acid in your stomach. This effect helps heal and prevent ulcers and improves symptoms such as heartburn and stomach pain.

4.2 Posology and method of administration

Cimetidine is injected into a vein or muscle as directed by your doctor, usually every 6 to 8 hours. When injected into a vein, cimetidine should be given slowly over at least 5 minutes. Giving the medication too fast may cause dizziness, irregular heartbeat, or a drop in blood pressure. The dosage and length of treatment are based on your medical condition and response to treatment. The dosage in children may also be based on body weight. Do not increase your dose, use this medication more often than prescribed, or stop using it without first consulting your doctor. If you are giving this medication to yourself at home, learn all preparation and usage instructions from your health care professional.

4.3 Contraindications

Cimetidine injection is contraindicated in patients allergic to this injection or other H2 blocker (e.g., ranitidine).

4.4 Special warnings and special precautions for use

Before using cimetidine, tell your doctor or pharmacist if you are allergic to it; or to other H2 blockers (e.g.,ranitidine); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk

to your medical history, especially of: heart problems(e.g., irregular heartbeat), immune system problems, kidney disease, liver problems, lung disease(e.g.,chronic obstructive pulmonary disease-COPD). This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side effects(e.g., confusion) while using this drug. During pregnancy, this medication should be used when clearly needed. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Consult your doctor before breast-feeding.

4.5 Interaction with other FPPs and other forms of interaction

cimetidine injection has interaction with tricyclic antidepressants, benzodiazepines, metoprolol, propranolol, carbamazepine, phenytoin, procainamide, quinidine, theophylline, valproic acid, azole antifungals and warfarin.

4.6 Pregnancy and lactation

During pregnancy, this medication should be used when clearly needed. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Consult your doctor before breast-feeding.

4.7 Effects on ability to drive and use machines

his drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely.

4.8 Undesirable effects

Headache, diarrhea, dizziness, drowsiness, and pain/redness at the injection site may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. A very serious allegic reaction, including: rash, itching/swelling (especially of the face /tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

4.9 Dosage and administration

Each 2mL ampoule contains 400mg cimetidine

To be adjusted according to physiopathologic status. Daily doses to be administered in 2-3 divided doses. i/m injection is possible although may be painful. i/v use is recommended:

Discontinuouse: at regular intervals; 0.5-1 ampoules diluted in infusion liquid; rate of infusion:≤200mg/hour for 2 hours.

Continuous: rate of infusion: ≤75mg/hour for 24 hours.

Avoid direct i/v injection in patients suffering from cardiopathy. If needed, per 200mg to be diluted in 20ml of an appropriate solution and injected slowly(over at least 5 minutes).

Adults: 0.8-1.6g/day(2-4 ampoules/24 hours)

Children: treatment of gastro-duodenal ulcer and oesophagitis:

Newborn: 5mg/kg/day

Infants less than 1 year of age: 20 mg/kg/day;

Children fromm 1 to 12 years of age: 20-30 mg/kg/day.

Gastro-duodenal ulcer: 800 mg/day.

Oesophagitis: 800-1600mg/day depending on severity of lesions.

Zollinger-Ellison syndrome: Dose may be increased, if needed, up to 2g/day.
Renal impairment: reduce dose as follows according to creatinine clearance (CrCl):
CrCl 0-15 ml/min: 200 mg every 12 hours.
CrCl 15-30 ml/min: 200 mg every 12 hours.
CrCl 30-50 ml/min: 200 mg every 12 hours.
Severe hepatic impairment: reduce dose; maximum dose 600 mg/day. Do not share this medication with others. For best results, this medication is often used along with lifestyle changes such as stress-reduction programs, exercise, and diet changes. Talk to your health care professional about changes that might benefit you. Laboratory and/or medical tests(e.g.,endoscopy, kidney function tests) may be performed to monitor your progress or check for side effects.

4.10 Overdose

Not applicable

5. Pharmcological properties

5.1. Pharmacodynamics properties

Cimetidine is known as an H2 histamine blocker. It works by reducing the amount of acid in your stomach. This effect helps heal and prevent ulcers and improves symptoms such as heartburn and stomach pain.

5.2. Pharmacokinetic properties

Cimetidine is injected into a vein or muscle as directed by your doctor, usually 6 to 8 hours, when injected into a vein, cimetidine should be given slowly over at least 5 minutes. Giving the medication too fast may cause dizziness, irregular heartbeat, or a drop in blood pressure.

5.3. Preclinical safety data

As part of this application, carcinogenicity studies were not conducted. Previous preclinical studies (recommended prescription amounts of lithium carbonate) did not show the potential risk of carcinogenesis.

6. Pharmaceutical particulars

6.1 List of excipients

Excipients for Cimetidine injection:

Hydrochloride acid	USP
Water for injection	USP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store below 30℃， protect from light

6.5 Nature and contents of container

2mL; Single dose vial packaged in carton of 10 ampoules.

6.6 Instructions for use and handling

Keep the medicine out reach of children.

7. Marketing authorization holder

Name: Humanwell Pharmaceutical Ethiopia PLC.
Address: Tuleffa kebele, Hageremariam Kessem worda, Northern shoa zone Amara Region, Ethiopia
Tel: +251 118901826 +251 118903393

E-mail: tangyuzhong@renfu.com.cn chengpeng@renfu.com.cn

8. Numbers in the national register of finished pharmaceutical products

Not applicable.

9. Date of first authorization/renewal of the authorization

Not applicable.

10. Date of revision the text

Not applicable.