Summary of Product Characteristics

1. Name of drug prodcut

Brand name: Mederax
Product name: Metoclopramide Hydrochloride tablet 10mg
Strength: 10mg
Pharmaceutical dosage form: Tablet

2. Qualitative and quantitative compositions

Each tablet contains:
Metoclopramide Hydrochloride10mg

Commercial batch size: 510,000 tablets

Batch formula for production batches

No.	Ingredient	Quantity per batch (kg)	Overages	Function
Active substance:				
1	Metoclopramide Hydrochloride	5.1		API
2	Microcrystalline cellulose	17.85		Disintegrant
3	Maize Starch	24.48		Filler
4	Dextrin	12.24		Filler
5	Sucrose	7.14		Corrigent
6	PVPK30	1.02		Adhesives
7	Silicon Dioxide	2.55		Lubricant
8	Magnesium stearate	1.02		Lubricant

3. Pharmaceutical Form
White, round tablet.

4. Clinical particulars

4.1 Therapeutic indications
It is used as an adjunct to the X-ray examination of the stomach and duodenum and post-operative hypotonia (postvagotomy syndrome).

It is also used as an anti-emetic for the prevention and treatment of irradiation sickness, post-operative vomiting, and drug-induced nausea and vomiting.

4.2. Posology and method of administration
Adults:

The average adult dose is 10 mg eight hourly.

In diagnostic radiology and duodenal intubation: 20 mg before the barium meal.

Children:

5-14 years: 2,5 - 5 mg three times daily.

3-5 years: 2 mg two to three times daily.

4.3. Contra- indications

It should not be used where gastro-intestinal conditions might be adversely affected as in intestinal obstruction or immediately after surgery.
Patients with phaeochromocytoma, or convulsive disorders.

4.4 Special warning and General cautions
The use of metoclopramide throughout the duration of pregnancy is considered unsafe as teratogenicity has been demonstrated in animal studies.

4.5 Drug Interaction
Care should be exercised when concomitant medication that can also cause extrapyramidal side-effects such as the phenothiazines, are taken. Anticholinergic agents antagonise the effects of metoclopramide; narcotic analgesics may act similarly. Metoclopramide may affect the absorption of other medicines by either diminishing absorption from the stomach or by enhancing absorption from the small intestine.

4.6 Pregnacy and laction
The use of metoclopramide throughout the duration of pregnancy is considered unsafe as teratogenicity has been demonstrated in animal studies.

Metoclopramide has been found to be transferred to breast milk. It should therefore not be taken while breast feeding.
Griseofulvin crosses the placenta and it has been shown to be embryo toxic and teratogenic in rats.

4.7 Effects on ability to drive and use machines.
None

4.8 Undesirable effects
Metoclopramide may cause extrapyramidal symptoms which usually occur as acute dystonic reactions especially in young patients; the findings include spasm of facial and/or extra-ocular muscles, trismus, a bulbar type of speech and unnatural positioning of the head and shoulders. There may be a general increase in muscle tone.
Parkinsonism and/or tardive dyskinesia have occasionally occurred, usually during prolonged treatment in elderly patients. Other adverse effects include restlessness, drowsiness, dizziness, and bowel upsets such as diarrhoea or constipation. The hyperprolactinaemia which metoclopramide produces may result in breast engorgement and galactorrhoea or related disorders. The conditions return to normal after withdrawal of the medicine.
As both metoclopramide and the phenothiazines may cause transient dystonia, care should be exercised in the event of both medicines being prescribed concurrently.
Transient increases in plasma aldosterone concentrations have been reported.

4.9 Overdoses

The symptoms of overdosage are those stated under side-effects above and in these cases the dosage should be reduced or the medicine discontinued. Treatment is supportive and symptomatic.

5. Pharmacological properties
5.1 Pharmacodynamic
This drug is a dopamine receptor blocker, and its structure is similar to procainamide, without anesthesia and cardiac effects, vomiting and gastrointestinal tract having a powerful stimulant of the central town. The drug is mainly improves CTZ threshold by inhibiting central emetic chemosensory area (CTZ) dopamine receptors, the autonomic nervous afferent impulses decrease, thus showing a strong central antiemetic effect. Meanwhile, the drug inhibits gastric smooth muscle relaxation allows increased cholinergic gastrointestinal smooth muscle response, accelerate gastric emptying, increased gastric antrum relative activity. While promoting relaxation of the upper section of the small intestine, thus prompting the antrum, gastric body and functional coordination between the upper section of the small intestine. Esophageal reflux reduce the drug due to the lower esophageal sphincter resting pressure, esophageal peristalsis contraction amplitude increases, thus making the contents of the esophagus caused by clearance capacity enhancement. In addition, the drug still stimulate prolactin release.

5.2 Pharmacokinetics

The drug absorption from the gastrointestinal tract is easy, the main absorption site in the small intestine. Because the drug promote gastric emptying, so absorbing and rapid onset of 1-3 minutes after intravenous injection, intramuscular injection after 10-15 minutes, 30-60

minutes after oral administration of onset, duration of action is usually 1-2 hours. The drug has a first-pass effect of oral bioavailability of 70%, rectal bioavailability of 50% -100%, with an average bioavailability of intranasal administration of 50.5%, bioavailability and peak plasma concentrations have significant individual differences. After entering the blood circulation, 13% -22% of the drug rapidly bound to plasma proteins (mainly albumin). Metabolized by the liver, the half-life is generally 4-6 hours vary according to the size of the dose, the half-life in patients with renal failure or cirrhosis extended. This drug excreted by the kidneys, 85% about oral dose of the prototype and glucuronide conjugates with the urine, but also with milk excretion. Easily through the blood - brain barrier and the placental barrier.

6. Pharmaceutical particulars

6.1 List of excipient (s).
Microcrystalline cellulose,Maize Starch,Dextrin,Sucrose,PVPK30,Silicon Dioxide, Magnesium stearate

6.2. Shelf-life
36 months from manufactured date

6.3 Incompatibilities
N/A

6.4 Special precation for storag
1) Keep out of reach of children
2) Store at temperature below 30°C.

7. Marketing authorization holder

Manufacturer: Jiangsu Pengyao Pharmaceutical Co.Ltd.
Site of Manufacture: No.10,Chaquan Road,Yixing , Jiangsu Province, China.

8. Marketing authorization number

9. Date of first of authorization / renewal of authorization

10. Date of revision of the text

May,2020