Taj Pharmaceuticals Ltd.

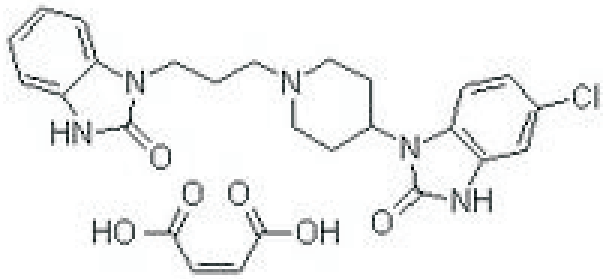
Domperidone Maleate

CAS No. : 99497-03-7

Identification

Synonyms 5-Chloro-1-[1-[3-(2-oxo-1,3-dihydrobenzoimidazol-1-yl)propyl]-4-piperidyl]-1, 3-dihydrobenzoimidazol-2-one maleate, Molecular Structure Domperidone maleate, 5-Chloro-1-[1-[3-(2-oxo-1,3-dihydrobenzoimidazol-1-yl)propyl]-4-piperidyl]-1, 3-dihydrobenzoimidazol-2-one maleate,

CAS Registry Number 99497-03-7
Molecular Formula C22H24ClN5O2.C4H4O4
Molecular Weight 541.99
Appearance: White or almost white powder
Use: Digestive system drugs
Standard: BP/USP/CP
Package: 25KG/Drum



Description

Domperidone is a peripheral dopamine antagonist structurally related to the butyrophenones with antiemetic and gastroprokinetic properties.

Domperidone effectively increases esophageal peristalsis and lower esophageal sphincter pressure (LESP), increases gastric motility and peristalsis, enhances gastroduodenal coordination and consequently facilitates gastric emptying and decreases small bowel transit time.

The mechanism of action of domperidone is related to its peripheral dopamine receptor blocking properties. Emesis induced by apomorphine, hydergine, morphine or levodopa through stimulation of the chemoreceptor trigger zone (situated outside the blood-brain barrier) can be blocked by domperidone. There is indirect evidence that emesis is also inhibited at the gastric level, since domperidone also inhibits emesis induced by oral levodopa, and local gastric wall concentrations following oral domperidone are much greater than those of the plasma and other organs. Domperidone does not readily cross the blood-brain barrier and therefore is not expected to have central effects.

Domperidone elevates serum prolactin levels but has no effect on circulating aldosterone levels.

Warnings

In Clinical States: Dopamine receptor blocking agents elevate prolactin levels; the elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported, the clinical significance of elevated serum prolactin levels is unknown for most patients. An increase in mammary neoplasms has been found in rodents after chronic administration of dopamine receptor blocking agents. Neither clinical studies nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these drugs and mammary tumorigenesis. The available evidence is considered too limited to be conclusive at this time.

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Precautions

In the event that the patient develops galactorrhea and/or gynecomastia, withdrawal of the drug will result in alleviation of these symptoms.

Drug Interactions

The concomitant administration of anticholinergic drugs may compromise the beneficial effects of domperidone. Since domperidone enhances gastric and small intestinal motility, it may accelerate absorption of drugs from the small bowel while slowing absorption of drugs taken up from the stomach, particularly those with sustained-release or enteric-coated formulations.

Care should be exercised when domperidone is administered in combination with MAO inhibitors.

The concomitant administration of domperidone maleate with antacids or H2-receptor blockers does not decrease the absorption of domperidone.

Dosage And Administration

Upper Gastrointestinal Motility Disorders: The usual dosage in adults is 10 mg orally 3 to 4 times a day, 15 to 30 minutes before meals and at bedtime if required. In severe or resistant cases the dose may be increased to a maximum of 20 mg 3 to 4 times a day.

Nausea and Vomiting Associated with Dopamine Agonist Antiparkinsonian Agents: The usual dosage in adults is 20 mg orally 3 to 4 times a day. Higher doses may be required to achieve symptom control while titration of the antiparkinsonian medication is occurring.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
This leaflet was prepared by
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Mumbai (India).
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