1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS : S4

PROPRIETARY NAME (AND DOSAGE FORM):

ADCO-CONTROMET® TABLET (TABLET)

ADCO-CONTROMET® SYRUP (SYRUP)

COMPOSITION:

ADCO-CONTROMET® TABLET:

Each tablet contains:

Metoclopramide monohydrochloride	10 mg

Sugar free

List of excipients: Magnesium stearate, Microcrystalline cellulose, Colloidal silicon dioxide and Sodium starch glycollate.

ADCO-CONTROMET® SYRUP:

Each 5 ml contains:

Metoclopramide monohydrochloride	5 mg
Preservatives:	
Methylparaben	0,2 % *m/v*
Propylparaben	0,04 % *m/v*
Contains sugar: Sucrose	2,50 g

Alcohol free

List of excipients: Cerise colourant, cherry flavourant, citric acid, glycerol and purified water.

PHARMACOLOGICAL CLASSIFICATION:

A: 11.2 Medicines acting on gastrointestinal tract: Gastrointestinal antispasmodics and cholinolytics (anticholinergics)

PHARMACOLOGICAL ACTION:

Metoclopramide acts on the chemoreceptor trigger zone to produce an anti-emetic effect. It also has a peripheral action which alters upper gut motility, increasing stomach peristalsis and emptying, as well as relaxing the pyloric antrum and duodenal cap. Gastric secretion is unaffected. The direct effects on the gut are antagonized by atropine and other anticholinergics. Metoclopramide causes a marked increase in the amplitude, frequency and duration of gastric contractions. The action of metoclopramide is not affected by vagotomy.

Metoclopramide is well absorbed following oral and rectal administration.

INDICATIONS:

ADCO-CONTROMET® 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.

CONTRAINDICATIONS:

ADCO-CONTROMET® should not be used where gastrointestinal conditions might be adversely affected as in intestinal obstruction or immediately after surgery.

Patients with phaeochromocytoma or convulsive disorders.

WARNINGS:

WARNING: TARDIVE DYSKINESIA

Chronic treatment with **ADCO-CONTROMET®** can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. The elderly, especially elderly women, are most likely to develop this condition.

ADCO-CONTROMET® therapy should routinely be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia, however, in some patients symptoms may lessen or resolve after **ADCO-CONTROMET®** treatment is stopped.

Prolonged treatment (greater than 12 weeks) with **ADCO-CONTROMET®** should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.

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

DOSAGE AND DIRECTIONS FOR USE:

Adults:

The average adult dose is 10 mg eight hourly.

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

Children:

5 to14 years: 2,5 to 5 mg three times daily.

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

(See **'WARNINGS')**

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

Tardive dyskinesia has been reported. See **'BOXED WARNINGS'**.

ADCO-CONTROMET® may cause extrapyramidal symptoms which usually occur as dystonic reactions, especially in young patients. Parkinsonism and/or tardive dyskinesia may occur, usually during prolonged treatment in elderly patients.

Bowel upsets such as diarrhoea or constipation, drowsiness and fatigue, dizziness, restlessness and anxiety, galactorrhoea and gynaecomastia may also occur. Transient increases in plasma aldosterone concentrations have been reported. Hypertensive crises have occurred in patients with phaeochromo-cytoma.

Children, young patients and the elderly should be treated with care. Patients on prolonged therapy should be reviewed regularly. Care should also be taken when **ADCO-CONTROMET®** is administered to patients with significant renal impairment or to those at risk of fluid retention as in hepatic impairment.

Care should be exercised when using **ADCO-CONTROMET®** in patients taking other drugs that can also cause extrapyramidal reactions, such as the phenothiazines. The effects of central nervous system depressants may be enhanced. Anticholinergic agents antagonise the effects of **ADCO-CONTROMET®**; narcotic analgesics may act similarly.

ADCO-CONTROMET® may affect the absorption of other drugs either by diminishing absorption from the stomach or by enhancing absorption from the small intestine. **ADCO-CONTROMET®** may also increase prolactin blood concentrations and therefore interfere with drugs that have a hypoprolactinaemic effect and with some diagnostic tests.

Special precautions:

Tardive dyskinesia (TD), a potentially irreversible and disfiguring disorder characterised by involuntary movements of the face, tongue or extremities, can develop in patients treated with **ADCO-CONTROMET®**. Although the risk of tardive dyskinesia (TD) **ADCO-CONTROMET®** has not been extensively studied, one published study reported a TD prevalence of 20 % among patients treated for at least 3 months.

The prevalence of the syndrome appears to be the highest among the elderly, especially elderly women. It is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.

There is no known effective treatment for established cases of tardive dyskinesia although the syndrome may remit, partially or completely, within several weeks to months after **ADCO-CONTROMET®** is withdrawn. **ADCO-CONTROMET®** itself, however, may suppress (or partially suppress) the signs of tardive dyskinesia, thereby masking the underlying disease process. The effect of this symptomatic suppression upon the long-term course of syndrome is unknown. Therefore, **ADCO-CONTROMET®** should not be used for the symptomatic control of tardive dyskinesia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms as under '**SIDE EFFECTS**'.

Treatment is symptomatic and supportive.

IDENTIFICATION:

ADCO-CONTROMET® TABLET: Round, white, normal convex, bisected tablet, 6,35 mm in diameter.

ADCO-CONTROMET® SYRUP: Cerise-coloured, mobile liquid with a cherry flavour and odour.

PRESENTATION:

ADCO-CONTROMET® TABLET: 100, 500 and 1 000 tablets packed in white polypropylene securitainers. Blister packs of 10's, 100's and 500's packed in PVC/Al and PVDC/Al. 1 000's in white cylindrical screw type HDPE containers with screw caps.

ADCO-CONTROMET® SYRUP: 50 ml packed in amber glass bottles.

STORAGE INSTRUCTIONS:

Store at or below 25 °C out of direct sunlight.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

ADCO-CONTROMET® TABLET: K/11.2/49

ADCO-CONTROMET® SYRUP: K/11.2/50

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