DOSAGE AND ADMINISTRATION:

The dosage recommendations given below should be strictly adhered to if side-effects of the dystonic type are to be avoided. It should be noted that total daily dosage of **METOMIDE** especially for children and young adults, should not normally exceed 0.5 mg/kg body weight.

Oral

Adults 15 years and over, weighing 60 kg or more,10 mg three times daily.

Adults 15 years and over, less than 60 kg body weight, 5 mg three times daily.

METOMIDE should only be used after careful examination to avoid masking an underlying disorder, e.g. cerebral irritation in the treatment of young adults and children attention should be given primarily to body weight and treatment should commence at the lower dosage where stated.

Children:

9-14 years	30 Kg and over	5 mg three times daily
5-9 years	20-29 Kg	2.5 mg three times daily.
3-5 years	15-19 Kg	2 mg two to three times daily.
1-3 years	10-14 Kg	1 mg two to three times daily.
under 1 year	up to 10 Kg	1 mg twice daily.

A liquid presentation should be used in younger age groups as this facilitates accurate dosage and administration.

I.M or I.V

METOMIDE may be administerd at the dosages stated above, either intramuscularly or by slow intravenous injection (1-2 minutes).

Radiological and Intubational Indications:

A single dose of Metomide may be given 5 - 10 minutes before examination. Subject to body weight considerations, (see above), the following dosages are recommended:

Adults:	20 years and over	10-20 mg
Young adults:	15-19 years	10 mg
Children:	9-14 years	5 mg
	5-9 years	2.5 mg
	3-5 years	2 mg
	under 3 years	1 mg

Indications for METOMIDE High Dose Intravenous Therapy:

Treatment of nausea and vomiting associated with intolerance cytotoxic drugs.

Dosage and administration: 2 mg/kg body weight by I.V infusion. It is recommended that each dose should be added to at least 50 ml of an appropriate diluent and infused over at least 15 minutes. The initial dose should be given prior to commencement of cytotoxic chemotherapy. Dosage may be repeated 2 hourly up to a maximum of 10 mg/kg body weight in any 24 hours period.

The cytotoxic agent should be administered as a separate infusion:

Stability in intravenous Solution:-

Intravenous solutions should be prepared as near as possible to the time of use. **METOMIDE** hes been shown to be stable in the solutions listed below for at least 24 hours at room temperature (25°C):

Sodium Chloride intravenous infusion B.P (0.9% w/v) Glucose intravenous infusion B.P (5% w/v) Sodium Chloride and Glucose intravenous infusion B.P (sod. chlor. 0.18% w/v, glucose 4% w/v) Compound Sodium Lactate Intravenous infusion B.P (Ringer - Lactate solution: Hartmann's solution)

COMPATIBILITY:

METOMIDE is compatible with morphine and pethidine. If the standard formulation of **METOMIDE** is used for the treatment of nausea and vomiting associated with cytotoxic drugs, the cytotoxic agent should be administered as a separate infusion.

PRESENTATION:

METOMIDE tablet 10 mg	:	Pack of 10 x 10 tablets.	**METOMIDE Syrup**	:	Bottle of 50 ml.
METOMIDE Injection 10 mg	:	Pack of 2 x 5 ampoules.			

SPECIAL PRECAUTIONS:

The use of **METOMIDE** in patients under 20 years should be restricted to the following: Severe intractable vomiting of known cause. Vomiting associated with radiotherapy and intolerance to cytotoxic drugs. As an aid to gastro-intestinal intubation and diagnostic radiology. As part of the premedication before surgical procedures.

If vomiting persists the patient should be re- assessed to exclude the possibility of an underlying disorder, e.g. cerebral irritation.

Following operations such as pyloroplasty or gut anastomosis **METOMIDE** therapy should be withheld for 3 to 4 days as vigorous muscular contractions may not help healing.

Since extra-pyramidal symptoms may occur with both **METOMIDE** and neuroleptics such as phenothiazines, particular care should be exercised in the event of these drugs being prescribed concurrently. The action of **METOMIDE** on the gastro-intestinal tract is antagonised by anticholinergics. The absorption of any concurrently administered oral medication may be modified by the effect of **METOMIDE** on gastric motility.

Use in Pregnancy: Animal tests in several mammalian species and clinical experience have not indicated a teratogenic effect. Nevertheless, **METOMIDE** should only be used when there are compelling reasons and it is not advised during the first trimester.

Abnormal renal or liver function: In patients with clinically significant degrees of renal or hepatic impairement oral, I.V or I.M therapy should be initiated at half the usual dose. Subsequent dosage will depend on individual clinical response.

Elderly patients: To avoid adverse reactions, adhere strictly to dosage recommendations where prolonged therapy is considered necessary, patients should be regularly reviewed.

Various extra-pyramidal reactions of **METOMIDE** usually, of the dystonic type, have been reportod, The incidence of these reactions, particularly in children and young adults is increased if daily dosages higher than 0.5 mg/kg body weight are administered. Dystonic reactions include: spasm of the facial muscles, trismus, rhythmic protrusion of the tongue, a bulbar type of speech, spasm of extra-ocular muscles including oculogyric crisis, unnatural positioning of the head and shoulders and opisthotonos. There may be a generalised increase in muscle tone.

The majority of reactions occur within 36 hours of starting treatment and the effect usually disappear within 24 hours of withdrawal of the drug. Should treatment of a dystonic reaction be required, an anticholinergic anti-Parkinsonian drug or a benzodiazepine may be used. Tardive dyskinesia has been reported during prolonged treatment in a small number of mainly elderly patients. Patients on prolonged treatment, should be regularly reviewed. Metoclopramide may induce an acute hypertensive response in patients with phaeochromocytoma. Raised serum prolactin levels have been observed during metoclopramide therapy. This effect is similar to that noted with many other compounds.

When given at high dose in connection with cancer chemotherapy **METOMIDE** has been well tolerated with few side-effects, the most common being mild sedation.

SIDE EFFECTS:

OVERDOSAGE:

Overdosage should be treated by gastric lavage with appropriate supportive measures. For treatment of a dystonic reaction see above.

STORAGE AND STABILITY:

All forms of **METOMIDE** should be protected from heat, sunlight & moisture and stored below 30°C. If **METOMIDE** ampoules are inadvertently exposed to light, any that show a yellow discolouration must be discarded. **METOMIDE** syrup may be diluted with Purified Water U.S.P but should then be used without delay. **METOMIDE** injection should not be diluted.

خوراک اور طریقہ استعمال: تجویز کردہ خوراک کی پوری طرح پابندی سے پٹھوں کے کھچاؤ جیسے بُرے اثرات سے بچا جا سکتا ہے۔ روزانہ خوراک کی کل مقدار ۵ء. ملی گرام فی کلوگرام جسمانی وزن سے زائد نہ ہو۔

منہ کے ذریعہ :

بالغان کے لیے : ۱۵ سال یا زائد عمر میں ۱۰ ملی گرام دن میں تین مرتبہ اگر جسمانی وزن ۶۰ کلوگرام یا اس سے زائد ہو لیکن ۵ ملی گرام دن میں تین مرتبہ اگر جسمانی وزن اس سے کم ہو۔ میٹومائڈ کو اچھی طرح معائنہ کے بعد ہی استعمال کرنا چاہیے تاکہ Cerebral irritation کی تشخیص کی مشکل سے چھپایا جا سکے۔ بالغ افراد اور بچوں کے علاج میں جسمانی وزن کو خاص طور سے مدِ نظر رکھنا چاہیئے۔ اور تجویز کردہ خوراک کی کم والی مقدار سے علاج شروع کرنا چاہیے۔

بچوں کے لیے :

۹ سال سے ۱۴ سال	۳۰ کلوگرام یا زائد	۵ ملی گرام دن میں تین مرتبہ	
۵ سے ۹ سال	۲۰ سے ۲۹ کلوگرام	۲ء۵ ملی گرام دن میں تین مرتبہ	
۳ سے ۵ سال	۱۵ سے ۱۹ کلوگرام	۲ ملی گرام دن میں دو سے تین مرتبہ	
۱ سے ۳ سال	۱۰ سے ۱۴ کلوگرام	۱ ملی گرام دن میں دو سے تین مرتبہ	
۱ سال سے کم	۱۰ کلوگرام تک	۱ ملی گرام دن میں دو مرتبہ	

چھوٹے بچوں کو شربت دینے سے آسانی ہوتی ہے۔

عضلاتی یا وریدی انجکشن

میٹومائڈ اوپر دی گئی مقداروں کے مطابق عضلاتی یا آہستہ وریدی انجکشن (۱۔۲ منٹ) سے بھی دی جا سکتی ہے۔

ریڈیولوجیکل اور اینڈیوسکوپک معائنہ کے دوران ہدایات : ان عوامل سے ۵۔۱۰ منٹ قبل جسمانی وزن کے لحاظ سے مندرجہ ذیل خوراک دی جاتی ہے۔

بالغ	۲۰ سال یا زائد	۱۰۔۲۰ ملی گرام	بچے	۹۔۱۴ سال	۵ ملی گرام
نوبالغ	۱۵۔۱۹ سال	۱۰ ملی گرام		۵۔۹ سال	۲ء۵ ملی گرام
				۳۔۵ سال	۲ ملی گرام
				۳ سال سے کم	۱ ملی گرام

بذریعہ وریدی زیادہ مقدار سے علاج کے لیے ہدایات : سائٹوٹوکسک دواؤں سے علاج کے دوران متلی اور قے کے علاج کے لیے یہ دوا ۲ ملی گرام فی کلوگرام جسمانی وزن کے لحاظ سے وریدی انفیوژن کے ذریعے دی جاتی ہے۔ یہ تجویز کیا جاتا ہے کہ ہر خوراک ۵۰ ملی لیٹر کے حساب سے محلول میں حل کر کے کم از کم ۱۵ منٹ میں دیں۔ پہلی خوراک سائٹوٹوکسک دواؤں سے پہلے دی جائے۔ خوراک کو ہر دو گھنٹے بعد دہرایا جا سکتا ہے اور دوا کی کل مقدار ۲۴ گھنٹے میں ۱۰ ملی گرام فی کلوگرام جسمانی وزن تک ہو سکتی ہے سائٹوٹوکسک دوا کو علیحدہ انفیوژن سے دیں۔

وریدی محلول میں استحکام : وریدی محلول کو جتنا ممکن ہو استعمال کے وقت ہی تیار کریں میٹومائڈ مجھے درج شدہ محلولات میں کمرہ کے درجہ حرارت (۲۵ڈگری سینٹی گریڈ) پر ۲۴ گھنٹے تک مستحکم رہتا ہے سوڈیم کلورائڈ وریدی انفیوژن ۔بی پی (۹ء۰ %w/v) گلوکوز وریدی انفیوژن۔ بی پی (۵ %w/v) سوڈیم کلورائڈ اور گلوکوز وریدی انفیوژن۔بی پی (سوڈیم کلورائیڈ ۱۸ء۰ %w/v گلوکوز ۴%w/v) سوڈیم لیکٹیٹ وریدی انفیوژن بی پی (ریگر۔ لیکٹیٹ محلول (ہارٹ مین)

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

133-C
25050-0002-002-0000-0000

METOMIDE® (METOCLOPRAMIDE HCI) میٹومائڈ

INTRODUCTION:

Metomide (Metoclopramide hydrochloride) regulates and synchronises gastro-intestinal motility anprevents pyloric and oesophageal reflux. It also has central and local anti-emetic action.

PHARMACOLOGY:

The action of Metomide is closely associated with parasympathetic nervous control of the upper gastro-intestinal tract, where it has the effect of encouraging normal peristaltic action. This provides for a fundamental approach to the treatment of those conditions where disturbed gastro-intestinal motility is a common underlying factor.

COMPOSITION:

TABLET: Each tablet contains: Metoclopramide HCl USP equivalent to Metoclopramide ..... 10 mg.
Product Specs.: USP
SYRUP : Each 5ml contains: Metoclopramide HCl USP equivalent to Metoclopramide ..... 5 mg.
Product Specs.: USP
AMPOULE: Each 2 ml contains: Metoclopramide HCl USP equivalent to Metoclopramide ..... 10 mg.
Product Specs.: USP

INDICATIONS:

Adults (20 years and over):

Digestive symptoms including:

Dyspepsia	Heartburn
Flatulence	Sickness
Regurgitation of bile	Pain

Digestive disorders associated with such conditions as:

Peptic ulcer	Doudenitis
Reflux oesophagitis	Hiatus hernia
Gastritis	Cholelithiasis and post-cholecystectomy dyspepsia
Post-vagotomy syndrome	Post-operative gastric hypotonia

Metomide promotes normal gastric emptying and restores motility in vagotomised patients. when post-operative symptoms suggest gastro-duodenal dysfunction.

Nausea and vomiting associated with:

Gastro-intestinal disorders
Cyclical vomiting
Intolerance to essential drugs including digitalis, antibacterial and cytotoxic drugs Congestive heart failure.
Deep X-ray or cobalt therapy.
Post-anaesthetic vomiting.

Diagnostic procedures:

Radiology	**METOMIDE** speed up the passage of barium meal by decreasing gastric emptying time, co-ordinating peristalsis and dilating the duodenal bulb.
Doudenal intubation	
Migraine	**METOMIDE** also facilitates duodenal intubation procedures. **METOMIDE** relieves symptoms of nausea and vomiting and over comes gastric stasis associated with migraine. This improvement in gastric emptying. assists the absorption of concurrently administered oral anti-migraine therapy (e.g. paracetamol) which may otherwise be impaired in such patients.