Cerucal® tablets

Please read this entire leaflet carefully before you start to take your medicine. It contains important information on what you should observe before taking this medicine. If you have more questions, please contact your doctor or pharmacist.

Patients information leaflet  Please, read carefully!

Cerucal® tablets

Qualitative and quantitative composition

Active ingredient:
1 tablet Cerucal® contains 10.54mg metoclopramide hydrochloride.1H2O (equal to 10mg metoclopramide hydrochloride, anhydrous).

Excipients:
Potato starch, lactose 1H2O, gelatin, magnesium stearate, precipitated silicon dioxide

Pharmaceutical form and quantity in each pack
Tablets

Name and address of the Marketing Authorization holder
AWD.pharma GmbH & Co. KG
Wasastrasse 50, 01445 Radebeul, Germany

Clinical particulars
Cerucal® stimulates the motility of the stomach and intestine (the ability for spontaneous movement) and prevents nausea and vomiting.

Therapeutic Indications
- motility disturbances of the upper gastro-intestinal tract
- nausea, retching and vomiting (with liver and kidney diseases, skull and brain injuries, migraine and drug intolerance)
- diabetic gastroparesis.

Contraindications
In what cases you should not take this medicine?
Metoclopramide must not be used in the following cases:
- known hypersensitivity to metoclopramide or one of the other components
- prolactin-dependent tumours
- tumours of the medulla of the adrenal glands (phaeochromocytoma)
- mechanical ileus
- intestinal perforation
- haemorrhages in the gastro-intestinal region
- on epileptics
- patients with extrapyramidal motor disorders
- while breastfeeding
- children (please refer to section What should be observed in children?)

Note:
Due to the contents of sodium sulphyte Cerucal® injection solution should not be administered to people with asthma or sulphyte hypersensitivity.
In which cases you should only take Cerucal® after consulting your doctor?
For patients with impaired hepatic function (severe hepatic insufficiency) and those with restricted renal function the dose has to be adapted to the functional disturbance (see section Posology, method and duration of therapy).

What should you observe during pregnancy?
Metoclopramide should not be used during the first 3 months of pregnancy and during lactation as sufficient studies have not been carried out. In the 2nd and 3rd trimesters of pregnancy metoclopramide should be used only on doctor’s orders on the basis of an exact diagnosis.

What should you observe in children?
Therapy with metoclopramide containing medications should be avoided in babies and children below 2 years of age. Children over 2 years up to 14 years of age should be given metoclopramide only on the basis of an exact diagnosis.

Special precautions for use
What special precautions should be observed during therapy with Cerucal®?
For patients with a restricted renal function and impaired hepatic function the dose has to be adapted to the functional disturbance (see section Posology, method and duration of therapy).
Special attention should be paid in epileptics and patients with porphyria. In adolescents and patients with a restricted renal function attention should be paid to adverse drug reactions due to poor excretion of metoclopramide. If such occur therapy with Cerucal should be stopped immediately (see also section Adverse drug reactions).

Interactions
Which other drugs modify the action of Cerucal®, or are modified by Cerucal®?
Metoclopramide may influence the absorption of other medicines, e.g. the absorption of digoxin and cimetidine may be reduced, while that of antibiotics (verified for tetracycline, pivampicillin), paracetamol, levodopa, lithium and alcohol may be speeded up or increased. Concurrent application of metoclopramide and lithium may lead to increased serum concentrations of lithium.

Anticholinergic agents may reduce the effect of metoclopramide.
Concurrent administration of metoclopramide and neuroleptics (such as phenothiazines, thioxanthene derivatives, butyrophenones) may increase the tendency to extrapyramidal disturbances (e.g. convulsions of the head, neck, shoulder region).
The effect of succinylcholine may be prolonged by metoclopramide.

Special note:
Sodium sulphite is a very reactive compound. It must therefore be expected that when administered together with the preparation, thiamin (vitamin B1) will be degraded.
Please, keep in mind that this information could be applied also to recently used medications.

What effects on the ability to drive and operate machines should be considered?
Even when taken according to directions, this drug may influence the patient’s reactions to the extent of impairing his or her ability to drive or to operate machines. In sudden unexpected situations your reactions might not be fast and focused enough. This risk is heightened in conjunction with alcohol and sedatives.

Posology, method and duration of therapy
Take Cerucal® exactly in accordance with the doctor’s instruction, otherwise it may not act properly.

How much Cerucal® should you take and how often?
**Adults and young people over 14 years:**

Unless otherwise prescribed, adults take 1 tablet of Cerucal 3 to 4 times daily (corresponding to 10 mg metoclopramide three to four times daily) and adolescents ½ to 1 tablet 2 to 3 times daily (corresponding to 5 to 10 mg metoclopramide 2 to 3 times daily).

**Children:**

In children over 2 years up to 14 years of age the dosage is 0.1 mg metoclopramide / kg BW as single dose, the maximum daily dose is 0.5 mg metoclopramide / kg BW. For this purpose, dosage forms (e.g. solution) which can be dosed more exactly, are available.

With a restricted renal function the dose has to be adapted to the functional disturbance.

The following figures hold for adults:

<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>Dose of metoclopramide</th>
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<tbody>
<tr>
<td>up to 10 ml/min.</td>
<td>1 tablet once a day (10 mg)</td>
</tr>
<tr>
<td>11 up to 60 ml/min.</td>
<td>1 tablet once a day (10 mg) and ½ tablet once day (5 mg)</td>
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</table>

For patients with a severe hepatic insufficiency with ascites the dose should be reduced by half because of the prolonged elimination half-life.

**Mode and duration of treatment**

The tablets should be taken unchewed before meals with some liquid.

The duration of treatment with Cerucal depends on the basic disease. 4 - 6 weeks are generally sufficient. A long-term treatment of up to 6 months is possible in exceptional cases.

**Note:**

On prolonged treatment with Cerucal the risk of the occurrence of movement disorders is increased (c.f. “Side effects”).

**Overdose and other possible mistakes**

**What should you know if during the therapy Cerucal® is overdosed (intentionally or by mistake)**

Somnolence, confusion, irritability, restlessness, convulsions, extrapyramidal motor disturbances, impairment of cardiovascular function associated with bradycardia and rise or drop in blood pressure

In single cases the occurrence of a condition called methemoglobinemia (reduced ability to transport oxygen, caused by chemical changes in the red blood cells) has been reported. In case of overdose, seek medical aid immediately!

The following measures could be undertaken as antidote therapy:

Extrapyramidal symptoms disappear after slow i.v. administration of biperiden. After intake of high doses gastric lavage, if necessary, may be carried out to eliminate metoclopramide from the gastrointestinal tract; medicinal charcoal and sodium sulfate may also be administered.

Monitoring of the vital functions until the symptoms disappear.

Detoxication (after oral application):

At high doses gastric lavage, activated charcoal and sodium sulphate, resp.
Undesirable effects
Which undesirable effects are possible during the treatment with Cerucal® and what measures could be undertaken?

On administration of metoclopramide diarrhoea, tiredness, headache, dizziness anxiety and restlessness may occur.

Seldom, skin rash may develop.
The occurrence of depressions has occasionally been observed on administration of metoclopramide.

In isolated cases, predominantly in children, a dyskinetic syndrome (spontaneous convulsive movements, especially in the head, neck and shoulder region) was found. This side effect manifests itself for instance as vertical or lateral gaze palsy, spasms of the facial or masticatory muscles, sticking out of the tongue, spasms of the pharynx and tongue muscles, wry posture or distortion of head and neck, over-stretching of the spine, flexion spasms of the arms, seldom stretch spasms of the legs. Antidote: Biperiden i.v.

In single cases, parkinsonism (tremor, rigor, akinesis) and late dyskinesia have been reported in elderly patients after long-term therapy.

Occasionally, a malignant neuroleptic syndrome has been observed on administration of metoclopramide (characteristic symptoms: temperature, muscular rigidity, altered consciousness and changes in blood pressure). The following emergency measures are recommended: discontinuation of Cerucal, cooling, dantrolene and/or bromocriptin, adequate liquid supply.

Prolonged administration may cause an increase in prolactin, gynaecomastia, galactorrhoea or menstruation disorders; in these cases drug treatment has to be interrupted.

In adolescents and patients with severe renal insufficiency showing a limited elimination of metoclopramide, the occurrence of side effects should carefully be noticed and the medicament immediately be withdrawn.

Inform your doctor or pharmacist if you notice any undesirable effects not enlisted in this package insert.

Expiry date
The expiry date of Cerucal® is marked on the flask and the folding box. Do not use the drug after the expiry date.

Special storage conditions
Store in temperature under 30º C!
Cerucal has to be kept protect from light.
Drug taken from the package should not be exposed to direct sunlight for any length of time.

Keep the drug out of the reach of children!

Date of last revision
November 2009