



PC.NO.8261

SCHEDULING STATUS [S4]

PROPRIETARY NAME AND DOSAGE FORM
METOCLOPRAMIDE 10 OETHMAAN tablets

COMPOSITION

Each **METOCLOPRAMIDE 10 OETHMAAN** TABLET contains:
 10 mg Metoclopramide hydrochloride.
 Contains sugar (lactose): 62 mg
 Excipients: Maize starch, lactose, povidone K30, magnesium stearate.

CATEGORY AND CLASS

A.5.7.2 Anti-emetics and anti-vertigo preparation.

PHARMACOLOGICAL ACTION**Pharmacodynamic Properties**

Metoclopramide hydrochloride belongs to the orthopramide series of synthetic compounds.

Gastrointestinal action:

Metoclopramide hydrochloride increases the number, mean strength and total activity of gastric antral contraction and also produces a significant increase in the strength of duodenal contractions.

These changes would all tend to increase the speed of gastric emptying, which has been observed radiologically and by other methods. Metoclopramide hydrochloride has no effect on gastric secretion or on the cardiovascular system.

Metoclopramide hydrochloride has an effect on the gastroesophageal junction of the stomach, producing an increase in cardiac sphincter pressure. The increase in pressure seen after metoclopramide hydrochloride is directly proportional to the initial resting pressure and minimal or absent in those with very low resting pressures.

The action of metoclopramide hydrochloride on the gastrointestinal tract is antagonised by atropine and other anticholinergic agents if they are administered in the previous 3 hours.

Anti-emetic action:

Metoclopramide hydrochloride has a central anti-emetic effect. The anti-emetic action of metoclopramide hydrochloride is not affected by atropine and other anticholinergic drugs.

Other action:

Metoclopramide hydrochloride stimulates prolactin secretion.

INDICATIONS

Digestive disorders:
 Metoclopramide hydrochloride is indicated in conditions associated with gastric stasis or hypomotility. It is useful in the management of postgastrotomy syndrome.

Nausea and vomiting:

Metoclopramide hydrochloride is indicated for the control of nausea and vomiting associated with the following conditions:
 drug-induced nausea and vomiting, uraemic conditions, malignant disease, gastrointestinal disorders and post-anaesthetic vomiting.

Diagnostic radiology:

Metoclopramide hydrochloride speeds gastric emptying and dilates the duodenal bulb. It is therefore useful in the following situations:

- Where barium meal studies are delayed by spasm of the duodenal cap making examination for the presence of an ulcer difficult.
- To facilitate examination of the hypotonic stomach with delayed emptying (gastric stasis and pyloric canal syndrome).
- To control or prevent nausea and vomiting of barium which occurs in a small minority of patients undergoing barium meal examination.

Duodenal intubation:

Metoclopramide hydrochloride is a useful aid to gastrointestinal intubation procedures.

CONTRAINDICATIONS

Hypersensitivity to metoclopramide or any ingredients included. (see **COMPOSITION**).

Two cases of hypertensive crises have reportedly been associated with metoclopramide hydrochloride after administration to patients with pheochromocytoma. Until further evaluation, metoclopramide hydrochloride should not be given to patients with suspected or confirmed pheochromocytoma.

WARNINGS AND SPECIAL PRECAUTIONS**WARNING: TARDIVE DYSKINESIA**

Chronic treatment with **METOCLOPRAMIDE 10 OETHMAAN** 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. **METOCLOPRAMIDE 10 OETHMAAN** 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 **METOCLOPRAMIDE 10 OETHMAAN** treatment is stopped. Prolonged treatment (greater than 12 weeks) with **METOCLOPRAMIDE 10 OETHMAAN** should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.

Care should be exercised in patient treated with other centrally active medicines e.g. epilepsy. In patients with clinically significant degrees of renal or hepatic impairment, therapy should be at a reduced dosage.

Special Precautions:

METOCLOPRAMIDE 10 OETHMAAN should not be used when stimulation of muscular contractions might adversely affect gastrointestinal conditions, as in gastrointestinal haemorrhage, obstruction, perforation or for a few days after surgery. Children, young adults and elderly should be treated with care as they are at increased risk of the extrapyramidal reactions. Patients on prolonged therapy should be reviewed regularly. Care should be exercised when **METOCLOPRAMIDE 10 OETHMAAN** is given to patients with renal, hepatic, epilepsy, asthma, Parkinsons disease or a history of depression or porphyria. Tardive dyskinesia (TD) (see Boxed Warnings), a potentially irreversible and disabling disorder characterized by involuntary movements of the face, tongue, or extremities, can develop in patient treated with **METOCLOPRAMIDE 10 OETHMAAN**. Although the risk of tardive dyskinesia (TD) with **METOCLOPRAMIDE 10 OETHMAAN** 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 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 **METOCLOPRAMIDE 10 OETHMAAN** is withdrawn.

METOCLOPRAMIDE 10 OETHMAAN 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, **METOCLOPRAMIDE 10 OETHMAAN** should not be used for the symptomatic control of tardive dyskinesia.

As both **METOCLOPRAMIDE 10 OETHMAAN** and the phenothiazines may cause transient dystonia, care should be exercised in the event of both medicines being prescribed concurrently.

Effects on the ability to drive and use of machines:

METOCLOPRAMIDE 10 OETHMAAN may cause drowsiness or impaired reactions, so affected patients should not drive or operate machinery.

Contains lactose.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucosegalactose malabsorption or fructose intolerance should not take

METOCLOPRAMIDE 10 OETHMAAN. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS

METOCLOPRAMIDE 10 OETHMAAN may affect the absorption of other medicines. It may either diminish absorption from the stomach (as with digoxin) or enhance absorption from small intestine (for example, with alcohol, cyclosporin, levodopa, aspirin or paracetamol). It inhibits serum cholinesterase and may prolong neuromuscular blockade produced by suxamethonium.

Since **METOCLOPRAMIDE 10 OETHMAAN** increase prolactin blood concentrations, it may interfere with medicines which have a hypoprolactinaemic effect such as bromocriptine. It should not be given to patients being treated with phenothiazines as extrapyramidal reactions may be precipitated. Increased toxicity may occur if **METOCLOPRAMIDE 10 OETHMAAN** is given to patients receiving lithium. Caution is advisable with other centrally acting medicines such as antiepileptics. Giving **METOCLOPRAMIDE 10 OETHMAAN** with Central Nervous System medicines can lead to increased sedative effects. Opioids and antimuscarinics antagonize the gastrointestinal effects of **METOCLOPRAMIDE 10 OETHMAAN**.

HUMAN REPRODUCTION

The use of metoclopramide hydrochloride is not recommended during pregnancy. **METOCLOPRAMIDE 10 OETHMAAN** is found in breast milk, the risk benefit must be considered.

The use of metoclopramide during pregnancy is considered unsafe as teratogenicity has been demonstrated in animal studies.

DOSAGE AND DIRECTIONS FOR USE

(See **WARNINGS AND SPECIAL PRECAUTIONS**)

Adults and children over 14 years:

10 mg (1 x 10 mg tablet) three times daily.

Children 5 to 14 years:

5 mg three times daily.

Children 3 to 5 years:

2.5 mg three times daily.

SIDE EFFECTS**Immune System disorders**

Less frequent occurrences of the neuroleptic malignant syndrome have been reported. This syndrome is potentially fatal and comprises hyperpyrexia, altered consciousness, muscle rigidity, autonomic instability and elevated levels of phosphokinase and must be treated urgently. Treatment must be stopped if this happens. Severe allergic reactions such as oedema of the tongue, peri-orbital oedema may occur.

Blood and Lymphatic system disorders

Agranulocytosis and methaemoglobinemia have been reported.

Cardiac disorders

Hypotension, hypertension and supraventricular tachycardia have been reported.

Endocrine disorders

Transient increases in plasma aldosterone concentrations have been observed. This may result in oedema with patients with congestive heart failure.

Nervous System Disorders

Subjective feelings of restlessness have been reported. These may be associated with overdosage. Extra-pyramidal dystonic-like reactions may occur; the findings include spasm of facial and/or extra-ocular muscles, trismus, a bulbous type of speech and unnatural positioning of the head and shoulders. There may be a general increase in muscle tone.

The majority of these reactions occur within 36 hours of starting treatment and disappear within 24 hours of withdrawal of the medicine. Should active therapy be required an anti-muscarinic anti-parkinson agent may be used.

Other side-effects include dizziness, faintness, agitation, anxiety, aggression.

Tardive dyskinesia has been reported. (See **Boxed Warnings**)

Gastrointestinal disorders

Metoclopramide hydrochloride may cause constipation, diarrhoea, drowsiness and lassitude.

Reproductive system and breast disorders

METOCLOPRAMIDE 10 OETHMAAN stimulates serum prolactin levels and may cause breast engorgement. The condition returns to normal after withdrawal of the medicine.

Skin and subcutaneous tissues

Skin rashes may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Overdosage with metoclopramide hydrochloride could give rise to dyskinetic reactions manifested as motor restlessness, agitation, irritability, spasm of facial and neck muscles and the muscles of the tongue. In severe cases opisthotonos can result. Anti-parkinson medications, e.g. procyclidine will usually control these reactions.

IDENTIFICATION

White, round, flat, bevel-edged tablets with a score line on the one side.

PRESENTATION

Amber plastic containers, amber glass containers, securtainers, sealed aluminium bags or blister packs of 10, 20 or 100 tablets. Amber plastic containers, amber glass containers, securtainers or blister packs of 500 or 1000 tablets.

STORAGE INSTRUCTIONS

Keep well-closed and store at or below 25°C in a dry place and protect from light.

KEEP OUT OF REACH OF CHILDREN**REGISTRATION NUMBER**

Q/5.7.2/228

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Oethmaan Biosims (PTY) Ltd

207A Sherwood House

Greenacres Office Park

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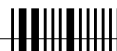
Victory Park, Johannesburg

2195

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

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07/2020 1222184





SKEDULERINGSSTATUS [S4]

BIENOMSNAAM EN DOSEERVORM
METOCLOPRAMIDE 10 OETHMAAN-tablette

SAMESTELLING

Elke METOCLOPRAMIDE 10 OETHMAAN-tablet bevat:
10 mg metoklopramidehidrochloried.
Bevat suiker (laktose); 62 mg
Hulpstowwe: mellesylsiel, laktose, povidoon K30, magnesiumstearaat.

KATEGORIE EN KLAS

A 5.7.2 Anti-emetika en anti-vertigomiddels

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe Metoklopramidehidrochloried behoort aan die bensamiedreks van sintetiese verbindings.

Gastro-intestinale werking:

Metoklopramidehidrochloried verhoog die aantal, gemiddelde sterkte en totale aktiwiteit van maag-antrale kontrakties en lever ook 'n beduidende verhoging in die sterkte van duodenale kontrakties.

Hierdie veranderinge verhoog almal die spoed van gastriese lediging, wat radiologies en met ander metodes waargeneem is. Metoklopramidehidrochloried het geen effek op gastriese sekresie of op die kardiovaskulêre stelsel nie.

Metoklopramidehidrochloried het 'n effek op die gastro-esofageale verbinding van die maag, wat 'n verhoging in druk op die onderste esofageale sfincter veroorsaak. Die toename in druk wat na toediening van metoklopramidehidrochloried gesien word, is direk eweredig aan die aanvanklike rustende druk en minimaal afwesig in diepene met baie lae rustende druk.

Die werking van metoklopramidehidrochloried op die spysverteringskanaal word deur atropien en ander anticholinergie middels toegewerk as dit in die vorige 3 uur toegedien word.

Anti-emetiese werking:

Metoklopramidehidrochloried het 'n sentrale anti-emetiese effek. Die anti-emetiese werking van metoklopramidehidrochloried word nie deur atropien en ander anticholinergie middels beïnvloed nie.

Ande werking:

Metoklopramidehidrochloried stimuleer prolaktiese sekresie.

INDIKASIES

Gastro-intestinale verstourings:

Metoklopramidehidrochloried is aangeel vir toestande wat met gastriese stase of hipomotiliteit gepaardgaan. Dit is nuttig in die bestuur van postvagotomie-sindroom.

Naarheid en braking:

Metoklopramidehidrochloried is aangeel vir die beheer van naarheid en braking wat met die volgende toestande gepaardgaan: middelgeduiseerde naarheid en braking, uremiese toestande, kwaadaardige siekte, gastro-intestinale afwykings en braking na narkose.

Diagnostiese radiologie:

Metoklopramidehidrochloried versnel maaglediging en ontspan die duodenumbol. Dit is dus nuttig in die volgende situasies:

- a) Waar maaglediging in bariummaalstudies vertraag word deur spasmas van die duodenale dop wat ondersoek vir die teenwoordigheid van 'n ulkus moeilik maak.
- b) Om ondersoek van die hipotoniese maag met vertraagde lediging (gastriese stase en piloriese kanaalsindroom) te fasiliteer.
- c) Om naarheid en braking van barium te beheer of te voorkom wat voorkom in 'n klein minderheid pasiënte wat ondersoek met 'n bariummaal ondergaan.

Duodenale intubasie:

Metoklopramidehidrochloried is 'n nuttige hulpmiddel vir gastro-intestinale intubasie-prosedures.

KONTRA-INDIKASIES

Hipersensitiewe teenoor metoklopramide of enige van die bestanddele (kyk SAMESTELLING).

Twee gevalle van hipertensiewe krisis is na berig met metoklopramidehidrochloried verbind na toediening aan pasiënte met feochromositoom. Tot verdere evaluering moet metoklopramidehidrochloried nie gegee word aan pasiënte met vermoedlike of bevestigde feochromositoom nie.

WAARSKUWINGS EN SPESIALE VOORSORGMATREELS:

WAARSKUWING-LAAT DISKINESIE

Chroniese behandeling met METOCLOPRAMIDE 10 OETHMAAN kan laat diskinesie veroorsaak. 'n ernstige bewegingsverstoring wat dikwels onomkeerbaar is. Die risiko vir die ontwikkeling van laat diskinesie neem toe met die duur van behandeling en die totale kumulatiewe dosis. Bejaardes, en veral bejaarde vroue, is meer geneig om hierdie toestand te ontwikkel. Behandeling met METOCLOPRAMIDE 10 OETHMAAN moet gereeld gestaak word vir pasiënte wat tekens of simptome van laat diskinesie ontwikkel. Daar is geen bekende behandeling vir laat diskinesie nie, hoewel die simptome minder kan word of heeltemal verdwyn as die antipsigotiese middel gestaak word. Langdurige behandeling (langer as 12 weke) met METOCLOPRAMIDE 10 OETHMAAN moet in alle gevalle vermy word, behalwe seldsame gevalle waar die terapeutiese voordeel vermoedelik die risiko's vir die pasiënt is om laat diskinesie te ontwikkel oorskry.

Wees versigtig met pasiënte wat met ander sentraalwerkende medisyne behandel word, bv. epilepsie.

Vir pasiënte met klinies beduidende grade van swak nier- of leverfunksie, moet die behandeling teen 'n lae dosis wees.

Spesiale voorsorgmaatreëls

METOCLOPRAMIDE 10 OETHMAAN moet nie gebruik word wanneer stimulasie van spierkontrakties gastro-intestinale toestand kan beïnvloed nie, soos met gastro-intestinale bloeding, obstruksie, perforasie of 'n paar dae na 'n operasie.

Kinders, jong volwassenes en bejaardes moet versigtig hanteer word, aangesien hulle 'n hoër risiko vir die ekstrapiramidale reaksies het.

Pasiënte wat langdurige behandeling kry, moet gereeld gemonitor word. Wees versigtig wanneer **METOCLOPRAMIDE 10 OETHMAAN** gegee word aan pasiënte met swak nier- of leverfunksie, met epilepsie, asma, Parkinson se siekte of 'n geskiedenis van depressie of portlie.

Laat diskinesie (LD) (kyk "Waarskuwing" in die raam), 'n moontlike onomkeerbare en skandende siekte wat deur onwillekeurige bewegings van die gesig, tong of ledemate gekenmerk word, kan ontwikkel terwyl 'n pasiënt met **METOCLOPRAMIDE 10 OETHMAAN** behandel word. Alhoewel die risiko van laat diskinesie (LD) met **METOCLOPRAMIDE 10 OETHMAAN** nie breedvoerig bestudeer is nie, het 'n gepubliseerde studie 'n voorkoms van 20% gerapporteer onder pasiënte wat vir ten minste 3 maande behandel is.

Dit lyk asof die voorkoms van die sindroom die hoogste is onder bejaardes, en veral bejaarde vroue. Dit is onmoontlik om te voorspel watter pasiënte geneig sal wees om die sindroom te ontwikkel. Dit word geglo dat sowel die risiko om die sindroom te ontwikkel en die moontlikheid dat dit onkeerbaar sal raak, met die duur van behandeling en die totale kumulatiewe dosis toeneem.

Daar is geen bekende effektiewe behandeling vir gevestigde gevalle van laat diskinesie nie, alhoewel die sindroom binne enkele weke tot maande nadat **METOCLOPRAMIDE 10 OETHMAAN** onttrek is gedeeltelik of heeltemal kan terugkeer.

METOCLOPRAMIDE 10 OETHMAAN self kan egter die tekens van laat diskinesie onderdruk (of gedeeltelik onderdruk), en sodoende die onderliggende siekteproses maskeer. Die effek van hierdie onderdrukking van simptome van die sindroom oor 'n lang termyn is onbekend. Daarom moet **METOCLOPRAMIDE 10 OETHMAAN** nie gebruik word vir die simptomatiese beheer van laat diskinesie nie.

Omdat sowel **METOCLOPRAMIDE 10 OETHMAAN** as die fenotiasiene verbygaande distorie kan

veroorzaak, moet hierdie middels versigtig saam voorgeskryf word.

Effek op die vermoë om motor te bestuur of masjinerie te gebruik:

METOCLOPRAMIDE 10 OETHMAAN kan lomerigheid of verswakte reaksies veroorsaak, en aangeslote pasiënte moet dus nie 'n voertuig bestuur of masjinerie hanteer nie.

Bevat laktose.

Pasiënte met die skaars ooreftige toestand van onverdraagbaarheid van galaktose, die Laplandse laktose-intoleransie of wanabsorpsie van glukose/galaktose of met onverdraagbaarheid van fruktose, moet nie **METOCLOPRAMIDE 10 OETHMAAN** drink nie. Laktose kan 'n effek op die glukemiese beheer in pasiënte met diabetes mellitus hê.

INTERAKSIES

METOCLOPRAMIDE 10 OETHMAAN kan die absorpsie van ander medisyne beïnvloed. Dit kan absorpsie uit die maag of verlaag (soos saam met digoksien) of absorpsie vanaf dunderm verhoog (byvoorbeeld saam met alkohol, siklosporien, levodopa, aspirien of parasetamol).

Dit rem serumcholinestrase en kan die neuromuskulêre blokkade wat deur suksametonium geproduseer word, verlaag.

Aangesien **METOCLOPRAMIDE 10 OETHMAAN** konsentrasies van prolaktien in die bloed verhoog, kan dit inmeng met medisyne, soos bromokriptien, wat 'n hipoprolaktinemiese effek het. Dit moet nie gegee word aan pasiënte wat met fenotiasiene behandel word nie, aangesien ekstrapiramidale reaksies aangebring kan word. Erger toksisiteit kan voorkom as **METOCLOPRAMIDE 10 OETHMAAN** gegee word aan pasiënte wat litium ontvang. Wees versigtig met ander sentraalwerkende medisyne soos anti-epileptika.

Gee van **METOCLOPRAMIDE 10 OETHMAAN** saam met middels vir die sentrale senuestelsel kan tot sterker kalmerende effekte lei. Digidie en antimuskarinika antagoniseer die gastro-intestinale effekte van **METOCLOPRAMIDE 10 OETHMAAN**.

MENSLIKE VOORTPLANTING

Die gebruik van metoklopramidehidrochloried tydens swangerskap word nie aanbeveel nie. **METOCLOPRAMIDE 10 OETHMAAN** word in borsmelk aangeel en die risikovoordeel moet oorweeg word.

Die gebruik van metoklopramide tydens swangerskap word as onveilig beskou aangesien teratogenisiteit in diere-studies aangeel is.

DOSIS EN GEBRUIKSANWYSINGS

Kyk WAARSKUWINGS EN SPESIALE VOORSORGMATREELS.

Volwassenes en kinders ouer as 14 jaar:
10 mg (1 x 10 mg-tablet) drie keer per dag.

Kinders 5 tot 14 jaar
5 mg drie keer per dag.

Kinders 3 tot 5 jaar
2,5 mg drie keer per dag.

NEWE-EFFEKTE

Verstourings van immuunstelsel

Die voorkoms van die neuroleptiese kwaadaardige sindroom is minder dikwels aangemeld. Hierdie sindroom is moontlik doodelik en bestaan uit hiperpreksie, veranderde bewussyn, spieringiditeit, outonome instabiliteit en hoër vlakke van fosfolipase en dit moet dringend behandel word. Behandeling moet gestaak word as dit gebeur. Erge allergiese reaksies soos oedeem van die tong en peri-orbitale oedeem kan voorkom.

Verstourings van bloed en lymfatisiese stelsel

Agranulositose en methemoglobinemie is aangemeld.

Harverstourings

Hipotensie, hipertensie en supraventrikulêre tagikardie is aangemeld.

Verstourings van endokriestelsel

Verbygaande toenames in konsentrasies van aldosteron in plasma is waargeneem. Dit kan lei tot oedeem in pasiënte met kongestiewe hartversaking.

Verstourings van die sensustelsel

Subjektiewe gevoelens van rusteloosheid is aangemeld. Dit kan met oordosering gepaardgaan. Ekstrapiramidale distoniesagtige reaksies kan voorkom; die bevindings sluit in spasmas van die gesig- en/of ekstra-okulêre spiere, trismus, 'n bulbuspree spraak en onnatuurlike posisionering van die kop en skouers. Daar kan 'n algemene toename in spiertonus wees. Die meeste van hierdie reaksies kom binne 36 uur na die aanvang van behandeling en verdwyn binne 24 uur na die onttrekking van die medisyne. Indien aktiewe behandeling nodig is, kan 'n anti-muskarinika anti-parkinsonmiddel gebruik word. Ander newe-effekte is onder meer duiseligheid, swakheid, agitasie, angs, aggressie. Laat diskinesie is aangemeld (kyk "Waarskuwing" in die raam).

Gastro-intestinale verstourings

Metoklopramidehidrochloried kan hardwigheid, diarree, lomerigheid en lusteloosheid veroorsaak.

Verstourings van die voorplantingsstelsel en borste

METOCLOPRAMIDE 10 OETHMAAN stimuleer serumprolaktienvlakke en kan borsvergroting veroorsaak. Die toestand keer na die onttrekking van die medisyne terug na normaal.

Vel en subkutane weefsel

Veluitslag kan voorkom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Oordosering met metoklopramidehidrochloried kan aanleiding gee tot diskinesiese reaksies wat as motoriese rusteloosheid, agitasie, prikkelbaarheid, spasmas van gesig- en nekspiere en die spiere van die tong manifesteer. In ernstige gevalle kan opistotonos ontstaan. Anti-parkinsonmedisyne, bv. proklopridien sal hierdie reaksies gewoonlik beheer.

IDENTIFIKASIE

Wit, ronde, plat tablette met skuinse kante en 'n breeklyn op een kant.

AANBIEDING

Amber plastiekhouders, amber glashouders, sekuriteithouders, verskeie aluminiumsakkies of stutpakkie met 10, 20 of 100 tablette. Amber plastiekhouders, amber glashouders, sekuriteithouders, verskeie aluminiumsakkies of stutpakkie met 500 of 1000 tablette.

BEWARINGSINSTRUKSIES

Hoë dig geslote en berg teen of benede 25 °C in 'n koel, droë plek en beskerm teen lig. HOU BUITE BEREIK VAN KINDERS

REGISTRASIONOMMER

05.7.2/228

NAAM EN BESIGHEIDSAADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Oethma Biologics (EDMS) Bpk
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2195

DATUM VAN PUBLIKASIE VAN DIE PASIENTINLIGTINGSBLAD

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