English Language

Front

13/12/2023

6923

PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAMES (and dosage forms)
MAXOLON T (tablets);
MAXOLON S (syrup);
MAXOLON D (paediatric drops);
MAXOLON I (injection);
MAXOLON S5 (suppositories);
MAXOLON S10 (suppositories)

COMPOSITION
MAXOLON T
Tablets each containing the equivalent of 10 mg anhydrous metoclopramide monohydrochloride.

MAXOLON S
Syrup containing the equivalent of 5 mg anhydrous metoclopramide monohydrochloride per 5 ml, with methyl p-hydroxybenzoate B.P. 0,08 % *m/v* and propyl p-hydroxybenzoate B.P. 0,02 % *m/v* as preservatives.

MAXOLON D
Paediatric drops containing the equivalent of 1 mg anhydrous metoclopramide monohydrochloride per 1 ml, with methyl p-hydroxybenzoate B.P. 0,08 % *m/v* and propyl p-hydroxybenzoate B.P. 0,02 % *m/v* as preservatives.

MAXOLON I
Injection containing the equivalent of 10 mg anhydrous metoclopramide monohydrochloride per 2 ml, with sodium metabisulphite B.P. 0,148 % *m/v* as antioxidant.

MAXOLON S5
Suppositories containing 5 mg metoclopramide free base.

MAXOLON S10
Suppositories containing 10 mg metoclopramide free base.

PHARMACOLOGICAL CLASSIFICATION
A 5.7.2. Anti-emetics and antivertigo preparations.

PHARMACOLOGICAL ACTION
MAXOLON belongs to the orthopramide series of synthetic compounds.

MAXOLON is well absorbed by oral, subcutaneous, intramuscular, or rectal routes. Approximately 30 % of MAXOLON is excreted unchanged in the urine.

Gastrointestinal Action:
MAXOLON seems to sensitise tissues to the action of acetylcholine. MAXOLON increases the number, strength and activity of gastric antral contractions and also producing an increase in the strength of duodenal contractions. These changes increase the speed of gastric emptying and reduce reflux from the duodenum and the stomach into the oesophagus, which has been observed radiologically and by other methods. MAXOLON simultaneously increases the motor action of the small intestine which results in a decrease in the small bowel transit time. MAXOLON has no effect on gastric secretion.

MAXOLON has an effect on the gastro-oesophageal junction of the stomach, producing an increase in cardiac sphincter pressure.

Anti-Emetic Action:
MAXOLON acts on the chemoreceptor trigger zone to produce a central anti-emetic effect.

INDICATIONS
Adults (20 Years and Over):
Digestive Disorders:
MAXOLON is of value in conditions associated with gastric stasis or hypomotility.

Nausea And Vomiting:
MAXOLON is an effective anti-emetic agent used in the control of nausea and vomiting associated with the following conditions: intolerance to essential drugs possessing emetic properties, uraemic conditions, malignant disease, gastrointestinal disorders and post anaesthetic vomiting.

Diagnostic Radiology:
In patients where delayed gastric emptying interferes with radiological examination of the stomach and/or small intestine.

Duodenal Intubation:
The action of MAXOLON in promoting stomach emptying, combined with its anti-emetic effect, has proved a useful aid to gastrointestinal intubation procedures.

Young Adults and Children:
The use of MAXOLON in patients under 20 years should be restricted to the following:
- Severe intractable vomiting of known cause.
- As an aid to gastrointestinal intubation and diagnostic radiology.

CONTRAINDICATIONS
Animal tests in several mammalian species have shown no teratogenic effects but MAXOLON is not recommended during pregnancy.
Cases of hypertensive crises have been associated with metoclopramide after administration to patients with phaeochromocytoma. MAXOLON should not be given to patients with suspected or confirmed phaeochromocytoma.

Where stimulation of muscular contractions might adversely affect gastrointestinal conditions such as gastrointestinal obstruction or immediately after surgery.

Hypersensitivity to metoclopramide or any of the ingredients.

Patients with convulsive disorders.

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

Care should be exercised in patients being treated with other centrally active drugs e.g. in epilepsy.

Tardive dyskinesia has been reported during prolonged therapy and long-term treatment should be regularly reviewed, especially when used in elderly patients for long periods.

In patients with clinically significant degrees of renal or hepatic impairment, therapy should be at a reduced dosage.

Care should be taken when medication causing extrapyramidal side effects such as phenothiazines, are taken concomitantly.

The neuroleptic malignant syndrome has been reported with metoclopramide in combination with neuroleptics as well as with metoclopramide monotherapy (see **Side effects and Special Precautions**).

Following operations such as pyloroplasty or gut anastomosis, metoclopramide therapy should be withheld for three or four days as vigorous muscular contractions may not help healing.

MAXOLON I (metoclopramide) ampoules contain sodium metabisulphite, which can cause allergic-type reactions including anaphylactic symptoms and bronchospasm in susceptible people, especially people with a history of asthma or allergy.

DOSAGE AND DIRECTIONS FOR USE
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 the total daily dosage of MAXOLON, especially for children and young adults, should not normally exceed 0,5 mg/kg body mass.

MAXOLON 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 mass and treatment should commence at the lower dosage where stated.

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

Adults 15 years and over, with a mass of 60 kg or more:
10 mg (1 x 10 mg tablet or 10 ml of 5 mg/5 ml syrup) 3 times daily.

Adults 15 years and over, with a mass of less than 60 kg:
5 mg (0,5 x 10 mg tablet or 5 ml of 5 mg/5 ml syrup) 3 times daily.

Children 9 - 14 years (30 kg and over):
5 mg (0,5 x 10 mg tablet or 5 ml of 5 mg/5 ml syrup) 3 times daily.

Children 5 - 9 years (20 - 29 kg):
2,5 mg (2,5 ml of 5 mg/5 ml syrup) 3 times daily.

Children 3 - 5 years (15 - 19 kg):
2 mg (2 ml of 1 mg/1 ml drops) 2 - 3 times daily.

Children 1 - 3 years (10 - 14 kg):
1 mg (1 ml of 1 mg /1 ml drops) 2 - 3 times daily.

Children under 1 year (up to 10 kg):
1 mg (1 ml of 1 mg/1 ml drops) twice daily.

Per Rectum:
Adults 15 years and over, with a mass of 60 kg or more:
10 mg (1 x 10 mg suppository) 1 - 3 times daily.

Adults 15 years and over, with a mass of less than 60 kg:
5 mg (1 x 5 mg suppository) 1 - 3 times daily.

Children 9 - 14 years (30 kg and over):
5 mg (1 x 5 mg suppository) 1 - 3 times daily.

Children under 9 years:
No suitable preparation available.

Parenteral:
On no account should MAXOLON ampoules be diluted for injection since this will upset the isotonicity and stability of the drug.

Adults 15 years and over, with a mass of 60 kg or more:
10 mg (1 ampoule) 1 - 3 times daily I.V. or I.M. depending on the severity of the condition.

Adults 15 years and over, with a mass of less than 60 kg:
5 mg (1, 0 ml of a 10 mg/2 ml ampoule) I.V. or I.M. 1 - 3 times daily.

Children 5 - 14 years:
2,5 mg (0, 5 ml of a 10 mg/2 ml ampoule) I.V. or I.M. twice daily in a tuberculin syringe.

Children 3 - 5 years:
1 mg (0,2 ml of a 10 mg/2 ml ampoule) I.V. or I.M. twice daily in a tuberculin syringe.

Children 1 - 3 years:
0,5 mg (0, 1 ml of a 10 mg/2 ml ampoule) I.V. or I.M. twice daily in a tuberculin syringe.

Dosage for Diagnostic Radiology:
Intravenous:
10 - 20 mg (1 - 2 ampoules) 5 - 15 minutes before the barium meal.

Intramuscular:
10 - 20 mg (1 - 2 ampoules) 10 - 15 minutes before the barium meal.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Subjective feelings of restlessness have been reported. Anxiety, agitation may occur, especially after rapid injection. Rare cases of acute depression have been reported. Drowsiness has been reported less frequently. Headache and dizziness may also occur.

There have been reports of abnormalities of cardiac conduction (such as bradycardia and heart block) in association with intravenous metoclopramide.

Various extrapyramidal dystonic-like reactions could occur, especially in children and young adults. The findings include spasm of facial and/or extra ocular muscles, trismus, a bulbar type of speech and unnatural positioning of the head and shoulders. There may be a general increase in muscle tone.

Hypotension, hypertension may occur and there are isolated reports of blood disorders, hypersensitivity reactions, and urinary incontinence.

Parkinsonism has been reported during prolonged and long-term treatment should be regularly reviewed.

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 Creatinine phosphokinase and must be treated urgently (recognised treatments include dantrolene and bromocriptine). Metoclopramide should be stopped immediately if this syndrome occurs.

Diarrhoea or constipation have been reported. MAXOLON stimulates serum prolactin levels, and may cause breast engorgement, galactorrhoea, lactorrhoea or related disorders. The conditions return to normal after withdrawal of the drug.

Transient increases in plasma aldosterone concentrations have been observed. Methaemoglobinaemia has also been reported.

LACTATION:
Since metoclopramide is found in breast milk, the risk-benefit must be considered.

INTERACTIONS:
Anticholinergic agents and opioid analgesics may antagonise the gastrointestinal effects of metoclopramide. The effects of central nervous system depressants may be enhanced.

Metoclopramide may affect the absorption of other medicines by either diminishing absorption from the stomach or by enhancing absorption from the small intestine.

As both MAXOLON and the phenothiazines may cause dystonia, care should be exercised in the event of both drugs being prescribed concomitantly.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Overdosage of MAXOLON could give rise to the dyskinetic reactions manifested as motor restlessness, agitation, irritability, spasm of facial and neck muscles and the muscles of the tongue. In severe cases opisthotonus can result. Very seldomly AV block has been observed. Overdosage should be treated by gastric lavage with appropriate supportive measures. Should active therapy be required for a dystonic reaction, an anti-Parkinson drug may be used. Further treatment is symptomatic and supportive.

IDENTIFICATION
MAXOLON T
White to ivory white, circular biconvex tablet, scored on one side and engraved MAXOLON on the reverse side.

MAXOLON S
Clear, colourless, viscous liquid with a sweet citrus flavour and odour.

MAXOLON D
Clear, colourless, viscous liquid with a sweet citrus flavour and odour.

MAXOLON I
Clear, colourless liquid in well-marked snap ampoules.

MAXOLON S5
Off-white, torpedo-shaped suppositories.

MAXOLON S10:
Off-white, torpedo-shaped suppositories.

PRESENTATION
MAXOLON T
Securitainer containing 500 tablets.
Blister strips containing 10 tablets packed in cartons of 2 or 10 strips.

MAXOLON S
Bottles containing 50 ml and 100 ml syrup.

MAXOLON D
Bottle containing 15 ml paediatric drops. Calibrated pipette provided.

MAXOLON I
Packs of 10 glass ampoules each containing 10 mg/2 ml.

MAXOLON S5
Cartons containing 5 suppositories of 5 mg.

MAXOLON S10
Cartons containing 5 suppositories of 10 m g.

STORAGE INSTRUCTIONS
MAXOLON T
Keep tightly closed and store in a cool (below 25 °C), dry place.

MAXOLON S
Keep tightly closed and store in a cool (below 25° C) place. Protect from light.

MAXOLON D
Keep tightly closed and store in a cool (below 25° C) place. Protect from light.

MAXOLON I
Store in a cool (below 25° C) place. Protect from light. Should inadvertent exposure occur, reject any ampoules showing a yellow discolouration.

MAXOLON S5
Store in a cool (below 25° C), dry place.

MAXOLON S10
Store in a cool (below 25° C), dry place.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBERS
MAXOLON I C 919 (Act 101/1965)

REGISTRATION NUMBERS
MAXOLON S C/5.7.2/918
MAXOLON S5 H/5.7.2/200
MAXOLON S10 H/5.7.2/201
MAXOLON T C/5.7.2/0920
MAXOLON D C/5.7.2/1014

NAME AND BUSINESS ADDRESS OF THE APPLICANT
Trinity Pharma (Pty) Ltd.
3 Gwen Lane,
4th Floor,
Sandton,
Gauteng, 2031.

DATE OF PUBLICATION OF THIS PACKAGE INSERT
04 03.1994

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION:
www.trinitypharma.co.za

Claudia Law - Approved - 14.12.2023

Rusan Specification Checklist For Artwork		**CMYK / PANTONE**
Produt: Maxolon I Injection 10mg/2ml	**Date:** 13/12/2023	Black
Component: Leaflet	**Country:** South Africa	
SAP / Item Code: 20006923 / LLT682	**Commodity Code:** Ensa/lf/mxln/01	
Dimension: 350 x 210 mm	**Folding Size:** 87.5x52.5 mm	
Specification.: 40 GSM Bible Paper		
Reason for change: Text Matter revised		**Supersedes Commodity Code** Ensa/lf/mxln
Artwork Path: P:\Packaging-Dev\01 Product Artwork\Maxolon-I Injection (South Africa) - DDN		

Afrikaan Language

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VOUBILJET

SKEDULERINGSTATUS

S4

EIENDOMSNAME (en doseervorme)
MAXOLON T (tablette);
MAXOLON S (stroop);
MAXOLON D (pediatriese druppels);
MAXOLON I (inspuiting);
MAXOLON S5 (setpille);
MAXOLON S10 (setpille)

SAMESTELLING
MAXOLON T
Tablette wat elk die ekwivalent van 10 mg anhedriese metoklopramiedmonohidrochloried bevat.

MAXOLON S
Stroop wat die ekwivalent van 5 mg anhedriese metoklopramiedmonohidrochloried per 5 ml bevat, met metiel-p-hidroksiebensoaat B.P. 0,08 % *m/v* en propiel-p-hidroksiebensoaat B.P. 0,02 % *m/v* as preserveermiddels.

MAXOLON D
Pediatriese druppels wat die ekwivalent van 1 mg anhedriese metoklopramiedmonohidrochloried per 1 ml bevat, met metiel-p-hidroksiebensoaat B.P. 0,08 % *m/v* en propiel-p-hidroksiebensoaat B.P. 0,02 % *m/v* as preserveermiddels.

MAXOLON I
Inspuiting wat die ekwivalent van 10 mg anhedriese metoklopramiedmonohidrochloried per 2 ml bevat, met natriummetabisulfiet B.P. 0,148 % *m/v* as anti-oksidant.

MAXOLON S5
Setpille wat 5 mg metoklopramied vrye basis bevat.

MAXOLON S10
Setpille wat 10 mg metoklopramied vrye basis bevat.

FARMAKOLOGIESE KLASSIFIKASIE
A 5.7.2. Anti-emetika en anti-vertigo preparate.

FARMAKOLOGIESE WERKING
MAXOLON behoort aan die ortopramiedreeks van sintetiese verbindings.
MAXOLON word goed geabsorbeer deur orale, subkutane, intramuskulêre of rektale roetes. Ongeveer 30 % van MAXOLON word onveranderd in die urine uitgeskei.

Gastroïntestinale werking:
Dit blyk dat MAXOLON weefsels sensitief maak vir die werking van asetielcholien. MAXOLON verhoog die aantal, sterkte en aktiwiteit van gastriese antrale kontraksies en veroorsaak ook 'n toename in die sterkte van duodenale kontraksies. Hierdie veranderinge verhoog die spoed van gastriese lediging en verminder refluks vanaf die duodenum en die maag in die esofagus, wat radiologies en deur ander metodes waargeneem is. MAXOLON verhoog terselfdertyd die motoriese aksie van die dunderm wat 'n afname in die dunderm-transittyd tot gevolg het. MAXOLON het geen effek op gastriese sekresie nie.

MAXOLON het 'n effek op die gastro-esofageale aansluiting van die maag, wat lei tot 'n toename in hartsfinkterdruk.

Anti-emetiese werking:
MAXOLON werk op die chemo-reseptor sneller sone om 'n sentrale anti-emetiese effek te produseer.

INDIKASIES
Volwassenes (20 jaar en ouer):
Spysverteringsteurnisse:
MAXOLON is van waarde by toestande wat geassosieer word met gastriese stase of hipomotiliteit.

Naarheid En Braking:
MAXOLON is 'n effektiewe anti-emetiese middel wat gebruik word in die beheer van naarheid en braking wat geassosieer word met die volgende toestande: onverdraagsaamheid teenoor noodsaaklike medisyne met emetiese eienskappe, uremiese toestande, maligne siektes, gastroïntestinale versteurings en braking na narkose.

Diagnostiese Radiologie:
By pasiënte waar vertraagde gastriese lediging inmeng met radiologiese ondersoek van die maag en/of dunderm.

Duodenale intubasie:
Die aksie van MAXOLON in die bevordering van gastriese lediging, gekombineer met die anti-emetiese effek daarvan, is 'n nuttige hulpmiddel vir gastrointestinale intubasie prosedures.

Jong Volwassenes en Kinders:
Die gebruik van MAXOLON by pasiënte onder 20 jaar moet beperk word tot die volgende:
- Erge, hardnekkige braking van bekende oorsaak.
- As 'n hulpmiddel vir gastrointestinale intubasie en diagnostiese radiologie.

KONTRAÏNDIKASIES
Dieretoetse in verskeie soogdierspesies het geen teratogeniese effekte getoon nie, maar MAXOLON word nie tydens swangerskap aanbeveel nie.
Gevalle van hipertensiewe krisisse is geassosieer met metoklopramied na toediening aan pasiënte met feochromositoom. MAXOLON moet nie aan pasiënte met vermoedelike of bevestigde feochromositoom gegee word nie.
Waar stimulasie van spiersametrekkings gastroïntestinale toestande nadelig kan beïnvloed soos by gastroïntestinale obstruksie of onmiddellik na chirurgie.
Hipersensitiwiteit vir metoklopramied of enige van die bestanddele.
Pasiënte met konvulsiewe versteurings.

WAARSKUWINGS
Indien braking voortduur, moet die pasiënt weer geassesseer word om die moontlikheid van 'n onderliggende versteuring uit te sluit, bv. serebrale irritasie.

Sorg moet aan die dag gelê word by pasiënte wat met ander sentraal aktiewe middels behandel word, bv. by epilepsie.

Tardiewe diskinesie is tydens langdurige terapie aangemeld en langtermynbehandeling moet gereeld hersien word, veral wanneer dit vir lang tydperke by bejaarde pasiënte gebruik word.

By pasiënte met klinies beduidende grade van renale- of hepatiese inkorting, moet terapie geskied teen 'n verlaagde dosis.

Sorg word aanbeveel wanneer medikasie wat ekstrapiramidale newe-effekte veroorsaak, soos fenotiasiene, gelyktydig geneem word.

Die neuroleptiese maligne sindroom is aangemeld met metoklopramied in kombinasie met neuroleptika sowel as met metoklopramied monoterapie (sien Newe-effekte en Spesiale Voorsorgmaatreëls).

Na operasies soos piloroplastiek of derm-anastomose, moet metoklopramiedterapie vir drie of vier dae weerhou word, aangesien kragtige spiersametrekkings nie genesing sal help nie.

MAXOLON I (metoklopramied) ampulle bevat natriummetabisulfiet, wat allergiese-tipe reaksies kan veroorsaak, insluitend anafilaktiese simptome en brongospasma by vatbare mense, veral mense met 'n geskiedenis van asma of allergie.

DOSIS EN GEBRUIKSAANWYSINGS
Die dosisaanbevelings wat hieronder gegee word, moet streng nagekom word om sodoende newe-effekte van die distoniese tipe te vermy.

Let daarop dat die totale daaglikse dosis van MAXOLON, veral by kinders en jong volwassenes, normaalweg nie 0,5 mg/kg liggaamsmassa moet oorskry nie.

MAXOLON moet slegs gebruik word na 'n noukeurige ondersoek om te verhoed dat 'n onderliggende versteuring, bv. serebrale irritasie, maskeer.

By die behandeling van jong volwassenes en kinders moet aandag primêr gegee word aan liggaamsmassa en behandeling moet begin word met die laer dosis waar aangedui.

Oraal:
'n Vloeibare aanbieding moet in die jonger ouderdomsgroepe gebruik word aangesien dit akkurate dosering en toediening vergemaklik.

Volwassenes 15 jaar en ouer, met 'n massa van 60 kg of meer:
10 mg (1 x 10 mg tablet of 10 ml van die 5 mg/5 ml stroop) 3 keer per dag.

Volwassenes 15 jaar en ouer, met 'n massa van minder as 60 kg:
5 mg (0,5 x 10 mg tablet of 5 ml van die 5 mg/5 ml stroop) 3 keer daagliks.

Kinders 9 - 14 jaar (30 kg en meer):
5 mg (0,5 x 10 mg tablet of 5 ml van die 5 mg/5 ml stroop) 3 keer daagliks.

Kinders 9 - 14 jaar (30 kg en meer):
5 mg (0,5 x 10 mg tablet of 5 ml van die 5 mg/5 ml stroop) 3 keer daagliks.

Kinders 5 - 9 jaar (20 - 29 kg):
2,5 mg (2,5 ml van die 5 mg/5 ml stroop) 3 keer per dag.

Kinders 3 - 5 jaar (15 - 19 kg):
2 mg (2 ml van die 1 mg/1 ml druppels) 2 - 3 keer daagliks.

Kinders 1- 3 jaar (10 - 14 kg):
1 mg (1 ml van die 1 mg/1 ml druppels) 2 - 3 keer daagliks.

Kinders onder 1 jaar (tot 10 kg):
1 mg (1 ml van die 1 mg/1 ml druppels) twee keer per dag.

Per rektum:
Volwassenes 15 jaar en ouer, met 'n massa van 60 kg of meer:
10 mg (1 x 10 mg setpil) 1 - 3 keer per dag.

Volwassenes 15 jaar en ouer, met 'n massa van minder as 60 kg:
5 mg (1 x 5 mg setpil) 1 - 3 keer per dag.

Kinders 9- 14 jaar (30 kg en meer):
5 mg (1 x 5 mg setpil) 1 - 3 keer per dag.

Kinders onder 9 jaar:
Geen geskikte voorbereiding beskikbaar nie.

Parenteraal:
MAXOLON-ampules moet in geen geval verdun word vir inspuiting nie, aangesien dit die isotonisiteit en stabiliteit van die medisyne sal versteur.

Volwassenes 15 jaar en ouer, met 'n massa van 60 kg of meer:
10 mg (1 ampul) 1 - 3 keer daagliks I.V. of I.M. afhangende van die erns van die toestand.

Volwassenes 15 jaar en ouer, met 'n massa van minder as 60 kg:
5 mg (1,0 ml van 'n 10 mg/2 ml ampul) I.V. of I.M. 1 - 3 keer daagliks.

Kinders 5- 14 jaar:
2,5 mg (0, 5 ml van 'n 10 mg/2 ml ampul) I.V. of I.M. twee keer per dag in 'n tuberkulienspuit.

Kinders 3- 5 jaar:
1 mg (0,2 ml van 'n 10mg/2 ml ampul) I.V. of I.M. twee keer per dag in 'n tuberkulienspuit.

Kinders 1- 3 jaar:
0,5 mg (0,1 ml van 'n 10mg/2 ml ampul) I.V. of I.M. twee keer per dag in 'n tuberkulienspuit.

Dosis vir Diagnostiese Radiologie:
Binneaars:
10 - 20 mg (1 - 2 ampulle) 5 - 15 minute voor die bariummaal

Binnespiers:
10 - 20 mg (1 - 2 ampulle) 10 - 15 minute voor die bariummaal.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Subjektiewe gevoelens van rusteloosheid is gerapporteer. Angs, agitasie kan voorkom, veral na vinnige inspuiting. Seldsame gevalle van akute depressie is aangemeld. Lomerigheid is minder gereeld aangemeld. Hoofpyn en duiseligheid kan ook voorkom. Daar is verslae van hartgeleidingsabnormaliteite (soos bradikardie en hartblok) in assosiasie met intraveneuse metoklopramied.

Verskeie ekstrapiramidale distoniese-tipe reaksies kan voorkom, veral by kinders en jong volwassenes. Die bevindinge sluit in spasma van gesigs- en/of ekstra okulêre spiere, trismus, 'n bulbêre tipe spraak en onnatuurlike posisionering van die kop en skouers. Daar kan 'n algemene toename in spiertonus wees.

Hipotensie, hipertensie kan voorkom en daar is geïsoleerde verslae van bloedversteurings, hipersensitiwiteitsreaksies en urinêre inkontinensie.

Parkinsonisme is aangemeld tydens langdurige en langtermynbehandeling. Dit behoort gereeld hersien te word.

Minder gereelde voorvalle van die neuroleptiese maligne sindroom is aangemeld. Hierdie sindroom is potensieel dodelik en word gekenmerk deur hiperpireksie, bewussynsverandering, spierrigiditeit, outonome onstabiliteit en verhoogde vlakke van kreatinienfosfokinase en moet dringend behandel word (erkende behandelings sluit dantroleen en bromokriptien in). Metoklopramied moet onmiddellik gestaak word indien hierdie sindroom voorkom.

Diarree of hardlywigheid is aangemeld. MAXOLON stimuleer serumprolaktienvlakke, en kan borsophoping, galaktorree, laktorree of verwante versteurings veroorsaak. Die toestande keer terug na normaal na onttrekking van die medisyne.

Verbygaande toenames in plasma-aldosteroonkonsentrasies is waargeneem.
Methemoglobinemie is ook aangemeld.

LAKTASIE:
Aangesien metoklopramied in borsmelk voorkom, moet die risiko-voordeel oorweeg word.

INTERAKSIES:
Anticholinergiese middels en opioïedanalgetika kan die gastroïntestinale effekte van metoklopramied teenwerk. Die effekte van sentrale senuweestelsel-depressante kan versterk word.

Metoklopramied kan die absorpsie van ander medisyne beïnvloed deur absorpsie uit die maag te verminder of deur absorpsie uit die dunderm te verbeter.
Aangesien beide MAXOLON en fenotiasiene distonie kan veroorsaak, moet versigtigheid aan die dag gelê word indien beide medisyne gelyktydig voorgeskryf word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Oordosering van MAXOLON kan aanleiding gee tot die diskinetiese reaksies wat gemanifesteer word deur motoriese rusteloosheid, agitasie, prikkelbaarheid, spasma van gesig- en nekspiere en die spiere van die tong. In ernstige gevalle kan opistotonos voorkom. AV-blok is baie selde waargeneem. Oordosering moet behandel word deur maagspoeling met toepaslike ondersteunende maatreëls. Indien aktiewe terapie benodig word vir 'n distoniese reaksie, kan 'n anti-Parkinson middel gebruik word. Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
MAXOLON T
Wit tot ivoor-wit, sirkelvormige bikonvekse tablet, gekeep aan die een kant en gegraveer MAXOLON op die ander kant.

MAXOLON S
Helder, kleurlose, viskose vloeistof met 'n soet sitrusgeur en -reuk.
MAXOLON D
Helder, kleurlose, viskose vloeistof met 'n soet sitrusgeur en -reuk.

MAXOLON I
Helder, kleurlose vloeistof in goed gemerkte snap-ampulle.

MAXOLON S5
Naaswit, torpedovormige setpille.

MAXOLON S10

AANBIEDING
MAXOLON T
Veiligheidshouer wat 500 tablette bevat.
Stulpstroke wat 10 tablette bevat verpak in kartonne van 2 of 10 stroke.

MAXOLON S
Bottels wat 50 ml en 100 ml stroop bevat.

MAXOLON D
Bottel wat 15 ml pediatriese druppels bevat. Gekalibreerde pipet verskaf.

MAXOLON I
Pakkies van 10 glasampulle wat elk 10 mg/2 ml bevat.

MAXOLON S5
Kartonne wat 5 setpille van 5 mg bevat.

MAXOLON S10
Kartonne wat 5 setpille van 10 mg bevat.

BERGINGSINSTRUKSIES
MAXOLON T
Hou styf toe en bêre in 'n koel (benede 25 °C), droë plek.

MAXOLON S
Hou styf toe en bêre in 'n koel (benede 25 °C) plek. Beskerm teen lig.

MAXOLON D
Hou styf toe en bêre in 'n koel (benede 25 °C) plek. Beskerm teen lig.

MAXOLON I
Bêre in 'n koel (benede 25 °C) plek. Beskerm teen lig. Indien onopsetlike blootstelling plaasvind, verwerp enige ampulle wat 'n geel verkleuring toon.

MAXOLON S5;
Bêre in 'n koel (benede 25 ° C), droë plek.

MAXOLON S10
Bêre in 'n koel (benede 25 ° C), droë plek

HOU BUITE BEREIK VAN KINDERS

VERWYSINGSNOMMERS
MAXOLON I C 919 (Wet 101/1965)

REGISTRASIENOMMERS:
MAXOLON S C/5.7.2/918
MAXOLON S5 H/5.7.2/200
MAXOLON S10 H/5.7.2/201
MAXOLON T C/5.7.2/0920
MAXOLON D C/5.7.2/1014

NAAM EN BESIGHEIDSADRES VAN DIE AANSOEKER
Trinity Pharma (Edms.) Bpk.
3 Gwen Lane,
4th Floor,
Sandton,
Gauteng, 2031.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
04 03.1994

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING:
www.trinitypharma.co.za

20006923
Ensa/lf/mxln/01