

SCHEDULING STATUS: Not scheduled

PROPRIETARY NAME (AND DOSAGE FORM):

ULTIMAG EFFERVESCENT TABLETS

COMPOSITION:

Each effervescent tablet contains:		% RDA
Soluble Magnesium Amino Acid Chelate	550 mg	
Equivalent to Magnesium	55 mg	18 %
Soluble Zinc Amino Acid Chelate	33 mg	
Equivalent to Zinc	5 mg	33,3 %

SUGAR FREE

Artificially sweetened with acesulfame K, saccharin and cyclamate.

PHARMACOLOGICAL CLASSIFICATION:

A 32.2 Other (Supplementary medicines)

INDICATIONS:

For the supplementation of magnesium and zinc in cases of insufficient intake.

CONTRA-INDICATIONS:

Renal impairment; dehydration and gastric lesions and disorders.

INTERACTIONS

No specific information about interactions with other medications is known. Magnesium should be given with caution to patients receiving digitalis glycosides. Concurrent administration with zinc might diminish the effect of penicillamine. Tetracyclines may form a chelate with zinc.

PREGNANCY AND LACTATION.

It is safe to take **Ultimag Effervescent Tablets** during pregnancy or while breast-feeding.

DOSAGE AND DIRECTIONS FOR USE:

Adults: Take 1 to 2 tablets dissolved in water daily.

Children: Half to one tablet dissolved in water daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Ultimag Effervescent Tablets are safe and there are no side-effects if taken as recommended. Magnesium should be given with caution to patients receiving digitalis glycosides.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms of hypermagnesemia may include the following:

flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest.

Treatment is symptomatic and supportive.

IDENTIFICATION:

Light-yellow effervescent tablets. The tablets effervesce in cold water to produce a yellow carbonated drink with a fresh lemon taste and smell.

PRESENTATION:

Ultimag Effervescent Tablets are supplied in plastic tubes each containing 15 tablets, and in a carton (30 tablets).

STORAGE INSTRUCTIONS:

Store below 25 °C in a cool dry place.
KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

CM16200/06

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Mirren (Pty) Ltd
18 Golden Drive
Morehill
Benoni
South Africa

DATE OF APPLICATION:

3 August 2006

ADDITIONAL PATIENT INFORMATION:

The symptoms of hypomagnesaemia (too little magnesium in your body) are, tiredness, lethargy, depression, poor sleeping habits, muscle cramps and tremors.

Most people who require a magnesium supplement will also require a zinc supplement:

1. People who require more magnesium and zinc are, pregnant and lactating women.
2. People who take in less magnesium and zinc are heavy drinkers and people on weight loss diets.
3. People who use or lose more magnesium and zinc are, sportspeople, people on diuretics, heavy bleeders and diabetics. (Diabetics should take **Ultimag** under doctor's supervision as it could lower diabetic therapy requirements).

Ultimag Effervescent Tablets are unique because the magnesium and zinc are in a **Soluble Chelated** form. Research results have shown that chelates yield more than double the absorption of magnesium and zinc when compared to the salts usually present in other supplements:

1. Chelates are formed when the magnesium and zinc are bound to carefully selected amino acids.
2. The body absorbs the chelates differently to mineral salts. That explains the enhanced minerals absorption.
3. The dosage for **Ultimag Effervescent Tablets** is therefore only one to two tablets daily for adults and half to one tablet for children, preferably at night.
4. Once absorbed, the body's enzyme systems free the mineral from the chelate structure for the cells to utilize.
5. Not all amino acid chelates are the same.
Ultimag Effervescent Tablets use patented soluble chelates for maximum absorption.
6. **Ultimag Effervescent Tablets** are a pleasant lemon flavoured drink when dissolved in a glass of water.
7. It is easy to administer **Ultimag Effervescent Tablets** to children and the elderly.
8. **Ultimag Effervescent Tablets** do not contain any:
 - Sugar
 - Gelatine or any animal products
 - Tartrazine or any artificial colourants
 - Preservatives

SKEDULERINGSSTATUS: Nie-geskeduleer

EIENDOMSNAAM (EN DOSEERVORM):

ULTIMAG BRUISTABLETTE

SAMESTELLING:

Elke bruistablet bevat:		% ADT
Oplosbare Magnesium Aminosuur Chelaat	550 mg	
Gelykstaande aan Magnesium	55 mg	18 %
Oplosbare Sink Aminosuur Chelaat	33 mg	
Gelykstaande aan Sink	5 mg	33,3 %

SUIKERVRY

Kunsmatig versoet met natrium asesulfaam, sakkarien en siklamaat.

FARMAKOLOGIESE KLASSIFIKASIE:

A 32.2 Ander (Supplementêre medisyne)

INDIKASIES:

Vir aanvulling van magnesium en sink waar onvoldoende inname voorkom.

KONTRA-INDIKASIES:

Nierontoereikendheid, dehidrasie en gastriese letsels en stoornisse.

INTERAKSIES:

Daar is geen spesifieke inligting bekend rondom die interaksies met ander geneesmiddels nie. Magnesium moet met omsigtigheid aan pasiënte wat hartglukosiede neem, gegee word. Gelyktydige toediening van sink met penisillamien kan die effektiwiteit van laasgenoemde verlaag. Tetrasiklien mag chelaat vorming van sink veroorsaak.

SWANGERSKAP EN BORSVOEDING:

Dit is veilig om **Ultimag Bruistablette** te neem tydens swangerskap en terwyl geborsvoed word.

DOSES EN GEBRUIKSAANWYSINGS:

Volwasseenes: Neem 1 tot 2 tablette opgelos in water daaglik.

Kinders: 'n Half tot een tablet opgelos in water daaglik.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Ultimag Bruistablette is veilig en het geen nuwe-effekte indien dit geneem word soos voorgeskryf nie. Magnesium moet met omsigtigheid aan pasiënte wat hartglukosiede neem, gegee word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Simptome van hipermagneseemie sluit die volgende in: blosing van die vel, dors, hipotensie a.g.v. vasodilatasie van die perifere vate, lomerigheid, verwarring, verlies aan tendonrefleks a.g.v. neurale blok, spiertamheid, asemhalingsonderdrukking, hartaritmieë, koma en hartstilstand. Behandeling is simptomeaties en ondersteunend.

IDENTIFIKASIE:

Liggeel bruistablette. Dit los op met opbruising om 'n liggeel gekarboneerde drankie te vorm met 'n vars suurleroem reuk en smaak.

AANBIEDING:

Ultimag Bruistablette word voorsien in plastiekbuise van 15 tablette elk, en in 'n karton (30 tablette).

BERGINGSAAANWYSINGS:

Berg by 'n temperatuur benede 25 °C op 'n koel droë plek.

HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNUMMER:

CM16200/06

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:

Mirren (Edms) Bpk

18 Goldenrylaan

Morehill

Benoni

Suid-Afrika

DATUM VAN AANSOEK:

3 Augustus 2006

AANVULLENDE PASIËNT INLIGTING

Die simptome van hipomagneseemie (te min magnesium in jou liggaam) is moegheid, lusteloosheid, neerslagtigheid, swak slaapgewoontes, spierkrampe en bewing.

Die meeste mense wat 'n magnesium aanvuller nodig het, sal ook 'n sink aanvuller benodig.

1. Mense wat meer magnesium en sink nodig het is swanger dames, en moeders wat borsvoed.
2. Mense wat minder magnesium en sink inneem is swaar drinkers en mense op 'n gewigsverlies dieet.
3. Mense wat meer magnesium en sink gebruik of verloor is sportlui, mense wat diuretika inneem, bloeiers en diabetese. (Diabete behoort **Ultimag** onder 'n mediese dokter se toesig te neem, aangesien dit die dosering van diabetiese behandeling kan verlaag.)

Ultimag Bruistablette is uniek want die magnesium en sink daarin is in 'n **oplosbare gecheleerde** vorm. Navorsing het bewys dat metale in die gecheleerde vorm meer as dubbel die hoeveelheid geabsorbeer word deur die liggaam indien dit vergelyk word met minerale soute wat gewoonlik in supplemente voorkom:

1. Chelaat word gevorm wanneer magnesium en sink gebind word aan geselekteerde aminosure.
2. Die liggaam absorbeer chelate op 'n ander wyse as metaalsoute. Dit verklaar die verhoogde absorpsie.
3. Die dosering van **Ultimag Bruistablette** is daarom slegs een tot twee tablette daaglik vir volwasseenes en 'n half tot een tablet vir kinders, verkieslik snags.
4. Die geabsorbeerde chelaat word deur die liggaam se ensiemstelsel verdeel om die metale vry te stel vir selgebruik.
5. Nie alle aminosuurchelate is dieselfde nie.

Ultimag Bruistablette gebruik gepatenteerde

oplosbare chelate vir maksimum absorpsie.

6. **Ultimag Bruistablette** gee 'n aangename suurleroem broisdrankie wanneer dit opgelos word in 'n glas water.

7. Dit is maklik om **Ultimag Bruistablette** vir kinders en bejaardes toe te dien.

8. **Ultimag Bruistablette** bevat niks van die volgende nie:

- Suiker
- Gelatien of enige ander dierprodukte
- Tartrasien of enige ander kunsmatige kleurstowwe
- Preserveermiddels