

# GELUSIL LIQUID

**SCHEDULING STATUS:** S2

**PROPRIETARY NAME AND DOSAGE FORM:**

**GELUSIL LIQUID**

**COMPOSITION:**

Each 5 ml of suspension contains:

Dicyclomine hydrochloride	2,50 mg
Aluminium hydroxide gel	200,00 mg
Light magnesium oxide	100,00 mg
Preservative: Nipasept	0,08% m/v

**PHARMACOLOGICAL CLASSIFICATION:**

A 11.2 Gastro-intestinal antispasmodics and cholinolytics

**PHARMACOLOGICAL ACTION:**

GELUSIL LIQUID has antacid properties.

**INDICATIONS:**

GELUSIL LIQUID is indicated as an antacid.

**CONTRA-INDICATIONS:**

Prostatic enlargement, paralytic ileus or pyloric stenosis where its use may lead to obstruction, severe ulcerative colitis, myasthenia gravis, glaucoma. Patients with renal failure. Obstructive uropathy, thyrotoxicosis, cardiac failure. Sensitivity to any of the ingredients.

**WARNINGS:**

GELUSIL LIQUID should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis and cardiac insufficiency or cardiac failure.

## **DOSAGE AND DIRECTIONS FOR USE:**

SHAKE THE BOTTLE BEFORE USE.

Adults: Two to four medicine measures (10-20 ml) one to two hours after meals and at bedtime or as needed for relief or as prescribed by your physician

Children over 2 years of age: One to two medicine measures (5-10 ml) one to two hours after meals and at bedtime or as needed for relief or as prescribed by your physician

## **SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Side-effects that may occur due to dicyclomine include dry mouth, blurred vision, flushing and dryness of skin, tachycardia with palpitations and arrhythmias, urinary retention and constipation.

Its effect may be enhanced by other drugs with anticholinergic properties. Fatigue, sedation, rash, thirst, nausea and vomiting, headache and dizziness have been reported.

Preparations containing dicyclomine should be used with caution in elderly men. 5-10% of magnesium is absorbed, and retention in patients with impaired renal function may lead to neurological, neuromuscular and cardiovascular impairment. The urine of normal persons may become alkaline which decreases excretion of drugs that are weak bases.

Magnesium may cause diarrhoea and mucosal irritation.

Aluminium hydroxide absorbs phosphates and excessive doses or normal doses with a low phosphate diet may lead to phosphate depletion with renal rickets or osteomalacia. Use with care in patients with hiatal hernia associated with reflux oesophagitis because anticholinergic drugs may aggravate the condition.

GELUSIL LIQUID may interfere with or reduce the absorption of anticholinergic medicines, barbiturates, digoxin, quinine, warfarin, tetracyclines and vitamins.

The effects of dicyclomine hydrochloride may be enhanced by the concomitant administration of anticholinergic medicines such as antihistamines, amantadine, butyrophenones, phenothiazines and tricyclic antidepressants.

## **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS**

### **TREATMENT:**

Toxic doses of dicyclomine cause tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement and hallucinations passing into delirium. A rash may appear on the face and upper trunk. In severe intoxication, depression of the central nervous system may occur with hypertension or circulatory failure and respiratory depression. See further under "Side-Effects and Special Precautions". Treatment is symptomatic and supportive.

### **IDENTIFICATION:**

A white homogenous suspension with a sweet orange taste and odour.

### **PRESENTATION:**

Round glass bottles of 200 ml

### **STORAGE INSTRUCTIONS:**

Store below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

### **REGISTRATION NUMBER:**

G/11.2/179

### **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE:**

Pharma Dynamics (Pty) Ltd

F02 Grapevine House

Steenberg Office Park

Westlake

7945

### **DATE OF PUBLICATION OF THIS PACKAGE INSERT**

May 2006

# GELUSIL LIQUID

**SKEDULERINGSSTATUS:** S2

**EIENDOMSNAAM EN DOSEERVORM:**

**GELUSIL LIQUID**

**SAMESTELLING:**

Elke 5 ml suspensie bevat:

Disiklomienhydrochloried	2,50 mg
Aluminiumhidroksiedjel	200,00 mg
Ligte magnesiumoksied	100,00 mg
Preserveermiddel: Nipasept	0,08% m/v

**FARMAKOLOGIESE KLASSIFIKASIE:**

A: 11.2 Gastroïntestinale antispasmodiese middels en cholienolitiese middels.

**FARMAKOLOGIESE WERKING:**

GELUSIL LIQUID besit teensuureienskappe.

**INDIKASIES:**

GELUSIL LIQUID word as 'n teensuurmiddel aangedui.

**KONTRA-INDIKASIES:**

Prostatiese vergroting, paralitiese ileus of piloriese stenose waar die gebruik daarvan mag lei tot obstruksie, ernstige ulseratiewe kolitis, myasthenia gravis, gloukoom. Pasiënte met nierversaking. Obstruktiwede uropatie, tirotoksikose, hartversaking. Sensitiwiteit teenoor enigeen van die bestanddele.

**WAARSKUWINGS:**

GELUSIL LIQUID moet met omsigtigheid gebruik word in toestande, soos tirotoksikose en kardiaal ontoereikendheid of hartversaking, wat deur tagikardie gekenmerk word.

**DOSERING EN GEBRUIKSAANWYSINGS:**

SKUD DIE BOTTEL VOOR GEBRUIK.

Volwassenes: Twee tot vier medisynemate (10-20 ml) een tot twee uur na maaltye en met slapenstyd of soos nodig vir verligting of soos deur die geneesheer voorgeskryf.

Kinders ouer:  
as 2 jaar Een tot twee medisynemate (5-10 ml) een tot twee uur na maaltye en met slapenstyd of soos nodig vir verligting of soos deur die geneesheer voorgeskryf.

### **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

Newe-effekte wat mag voorkom as gevolg van disiklomien sluit in droë mond, versteurde visie, blosing en droë vel, tagikardie met hartkloppings en aritmieë, urienretensie en hardlywigheid.

Die uitwerking daarvan mag deur ander geneesmiddels met anticholinergiese eienskappe versterk word.

Moegheid, kalmering, veluitslag, dors, naarheid en braking, hoofpyn en duiseligheid is aangemeld.

Preparate wat disiklomien bevat, moet met omsigtigheid in ouer mans gebruik word.

5-10% van die magnesium word geabsorbeer, en retensie in pasiënte met ingekorte nierfunksie mag tot neurologiese, neuromuskulêre en kardiovaskulêre inkorting lei.

Die urine van normale persone mag alkalies word wat die uitskeiding van geneesmiddels wat swak basisse is, verminder.

Magnesium mag diarree en irritasie van die slymvliese veroorsaak.

Aluminiumhidroksied absorbeer fosfate en oormatige dosisse of normale dosisse met 'n lae fosfaat-dieet mag tot uitputting van fosfaat met renale ragitis of osteomalasie lei. Gebruik met omsigtigheid in pasiënte met mantelvliesbreuk wat met refluks esofagitis geassosieer word omdat anticholinergiese geneesmiddels die toestand mag vererger.

GELUSIL LIQUID mag inmeng met die absorpsie van anticholinergiese medisyne, barbiturate, digoksien, kinien, warfarien, tetrasikliene en vitamene, of die absorpsie daarvan verminder.

Die uitwerkings van disiklomienhydrochloried mag versterk word deur gelyktydige toediening van anticholinergiese medisyne soos antihistamiene, amantadien, butirofenone, fenotiasiene en trisikliene antidepressante.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE  
BEHANDELING DAARVAN:**

Toksiese dosisse van disiklomien veroorsaak tagikardie, vinnige of snorkende asemhaling, hiperpireksie, rusteloosheid, verwarring en opgewondenheid en hallusinasies wat oorgaan na delirium. 'n Veluitslag mag op die gesig en boonste romp verskyn. In ernstige intoksikasie mag depressie van die sentrale senustelsel met hipertensie of sirkulatoriese versaking en respiratoriese depressie, voorkom. Sien verder onder "Nuwe-effekte en Spesiale Voorsorgmaatreëls". Behandeling is simptomeel en ondersteunend.

**IDENTIFIKASIE:**

'n Wit homogene suspensie met 'n soet lemoensmaak en -geur.

**AANBIEDING:**

Ronde glas bottels van 200 ml.

**BERINGSAAWYSINGS:**

Bewaar benede 25°C.

HOU BUITE BEREIK VAN KINDERS.

**REGISTRASIENOMMER:**

G/11.2/179

**NAAM EN BESIGHEIDSADRES VAN HOUER VAN DIE SERTIFIKAAT VAN  
REGISTRASIE:**

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**DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:**

May 2006