Specialist Information (Summary of product characteristics)

**Dysurgal® 0,5 mg**

1. **Name of the medicinal product**
   Dysurgal® 0,5 mg

2. **Qualitative and quantitative composition**
   Active agent: Atropine Sulphate
   Excipients see below 6.1.

3. **Dosage form**
   1 tablet contains: 0.5 mg Atropine Sulphate

4. **Clinical Information**

   4.1 **Indications**
   Spasms (colic) in the gastro-intestinal area as well as biliary and urinary tract; Inhibits secretions from the stomach and pancreas.

   4.2 **Posology and Method of administration**
   The dose should be administered individually. Unless otherwise prescribed the following recommendations apply:

<table>
<thead>
<tr>
<th>Age</th>
<th>Single dose</th>
<th>Daily total dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young children</td>
<td>1/2 Tablet (corresponding to 0.25 mg Atropine sulphate)</td>
<td>Up to 3 x 1/2 Tablets (Corresponding to 0.75 mg Atropine sulphate)</td>
</tr>
<tr>
<td>School children (6 – 14 years)</td>
<td>1 tablet (Corresponding to 0.5 mg Atropine sulphate)</td>
<td>Up to 3 x 1 Tablets (Corresponding to 1.5 mg Atropine sulphate)</td>
</tr>
<tr>
<td>Adolescents from 15 years and adults</td>
<td>1 – 2 Tablets (corresponding to 0.5 – 1 mg Atropine sulphate)</td>
<td>Up to 3 x 1 – 2 tablets (corresponding to 1.5 – 3 mg Atropine sulphate)</td>
</tr>
</tbody>
</table>

   Method of administration:
   Dysurgal® 0,5 mg tablets should be taken whole with some liquid (e.g. a glass of water).

   Duration of treatement:
   The duration of treatment depends on the duration of symptoms.

4.3 **Contraindications**

   Dysurgal® 0,5 mg should not be taken in:
   – Acute congestive glaucoma
   – Tachycardia with heart failure and thyrotoxicosis
- Tachycardiac cardiac arrhythmia
- Coronary stenosis
- Mechanical closing of the gastro intestinal tract
- Paralytic ileus
- With the occurrence of pathologically enlarged intestinal segments (megacolon)
- Obstructive urinary tract diseases
- Existing prostatic hypertrophy with postvoid residual urine
- Bladder emptying disorder with postvoid residual urine
- Myasthenia gravis
- Acute pulmonary oedema
- Pre-eclampsia
- Known oversensitivity to Atropine and other anticholinergics

4.4 Special warnings and precautions for use

Special care when taking Dysurgal® 0.5 mg is required with
a) Children and older people: infants and small children up to 2 years old as well as adults over 65 years are particularly sensitive to Atropine Sulphate. Dose adjustments may be required in this population.
b) Fever; may lead to heat stroke through reduced perspiration. Since Atropine sulphate affects the ability to regulate the temperature through reduction in sweat secretion, Dysurgal® 0.5 mg should only be used with care and under continuous monitoring of the body temperature in patients with fever and in high ambient temperature conditions. Sauna visits and hot baths should be avoided after taking Dysurgal® 0.5 mg.
c) In patients who have just suffered a heart attack, tachycardiac cardiac arrhythmias and ventricular fibrillations can occur when administering Atropine sulphate.
d) Heart failure, mitral valve stenosis, hypertension and hyperthyreosis: a dose of Dysurgal® 0.5 mg should be administered with care, to avoid the occurrence of Tachycardia (accelerated heart beat).
e) Downs-Syndrome

4.5 Interactions with other medications and other interactions

The anticholinergic effects of the following pharmaceuticals can be increased with the simultaneous use of Atropine sulphate:
- Antihistamines
- Neuroleptics (Phenothiazine, Butyrophenone)
- Tricyclic and tetracyclic antidepressants
- Pethidine
- Methylphenidate
- Antiparkinson’s medication with the exception of dopamine receptor agonists
- Antiarrhythmic such as chinidin, procaainamide und disopyramide
- Dopamine antagonists such as metoclopramide.

The simultaneous use of cisapride and atropine leads to a complete reversal of the effect of cisapride. As a result of atropine-reduced intestinal motility, the absorption of digoxin and nitrofurantoin are reduced whilst phenothiazines and levodopa are reabsorbed.
4.6 Pregnancy and lactation

Atropine sulphate passes through the placenta and is found in small quantities in breast milk. Dysurgal® 0.5 mg should only be used after rigorous risk-benefit assessment due to masking of bradycardia in the unborn child through atropine induced tachycardia.

The use of atropine in the last trimester of pregnancy, during birth and during caesarean section is contraindicated, since it can result in cardiac arrhythmia (in particular tachycardia) in the mother and child. There is risk of impairment of the autonomic nervous system which will affect the fetus and the adaptation of the new born baby after birth.

Breast feeding: contraindicated since Atropine Sulphate passes into breast milk.

In addition Atropine sulphate reduces milk production. If treatment with Dysurgal® 0.5 mg is required during the lactation period ablationation is recommended.

4.7 Effects on the ability to drive and operate machinery

This medication may, even when used as intended, alter the responsiveness to such an extent that, for example, the ability to react adequately to street traffic or to operate machinery is impaired. This is even more the case in combination with alcohol. Visual impairment over a long period of time (disturbances of accommodation) must be expected.

4.8 Undesirable effects

The following frequency information was established in specifying the side effects:

Very frequent: >1/10
Frequent: >1/100, <1/10
Occasionally: >1/1000, <1/100
Infrequently: >1/10 000, <1/1000
Very infrequently: <10 000

The side effects of Atropine sulphate are dependent on the dose.

Very frequent side effects: Mouth dryness, reduction of the sweat secretion (skin dryness; possible consequences: heat block, reddened skin), tachycardia, visual impairment following mydriasis and disorder of the accommodation.

Supra-ventricle and ventricle arrhythmia, shortening of the AV transition, muscle weakness and muscular coordination disorders, urination difficulties, disorders to the peristalsis, swallowing difficulties and gastro oesophageal reflux can occur. Speech disorders, states of restlessness and excitement, hallucinations, states of confusion, seizures, delirium and comatose states can occur.

A glaucoma attack can be triggered through atropine.

Angina pectoris complaints and a significant increase in blood pressure to hypertensive crisis were rarely observed.

Parotitis can develop as a consequence of the salivary secretion inhibitor with prolonged treatment.

A strong mydriasis and pronounced tachycardia can already occur even with low doses in patients with down’s syndrome.
Oversensitive reactions in the form of conjunctivitis, periocular dermatitis, pruritus, exanthema, erythema, urticarial can occur; it was very rare for an anaphylactic shock to be triggered.

4.9 Overdose

Typical symptoms of an overdose or poisoning are: blurred vision and photophobia following mydriasis and accommodative iridoplegia, dryness to the mouth, thirst and difficulty swallowing, dizziness, nausea, vomiting, dyspnoea, scarlet dehydrated skin, hyperthermia, heart beats, tachycardia, increased blood pressure, dermatome (Ileus), urge to urinate with simultaneously impeded urination (bladder atonia). Hyperthermia though inhibition of the sweat secretion and central impairment to the heat regulation can already occur in infants and small children with therapeutic dosing. Central symptoms are identified through motor agitation, states of excitement, seizures, disorientation, hallucinations and psychosis, similar to the picture of schizophrenia or alcoholic delirium. The central symptoms may progress into somnolence, coma and respiratory paralysis.

Therapy measures with overdosing:
Depending on the time and the severity of poisoning, induce vomiting and/or gastric lavage, and then add medical charcoal as absorbent and sodium sulphate as a laxative. Adults slowly receive 1 to 2 mg of physostigmine intravenously (if necessary repeat at hourly intervals) as an antidote. With central seizures and delirium 10 – 20 mg Diazepam i.v.
Children slowly receive 0.5 mg Physostigmine intravenously as antidote or intramuscular (if necessary repeat at hourly intervals). Initially 1 – 2 mg i.v with seizures and delirium. Artificial ventilation should be carried out in deep coma. Antipyretic (fever reducing) medication should not be given with hyperthermia (high body temperature), but heat dissipation should be carried out through physical measures (e.g. cold bath, changing packages, cold leg compression).

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

ATC-Code: A03BA01

Atropine is the racemate of D and L hyos-cyamine. L hyoscyamine occurs in different nightshade plants such as the deadly nightshade (Atropa belladonna) and razemises with the preparation of Atropine. L hyosycamine is mainly responsible for the peripheral parasympatholytic effect, since D hyoscyamin is 10 – 20 times less effective. Atropine acts as a competitive antagonist on muscular acetylcholine receptors. It is only at very high doses that the excitation transfer is inhibited on ganglia and neuromuscular endplates, mediated via nicotinic acetylcholine receptors. The most important pharmacological effects are tachycardia and a shortened AV transition through inhibition of the negative chronotropic and dromotropic effect of the acetylcholine on the heart, an inhibition of the salivary secretion, the motor function and the tonus of the gastrointestinal tract, an inhibition of the mucus secretion and the tonus of the bronchial tubes, an inhibition of the urinary bladder tonus as well as a mydriasis and accommodation paralysis on the eye.
5.2 Pharmacokinetic properties

Atropine sulphate is quickly and completely reabsorbed after subcutaneous and intramuscular application. The maximum plasma level is reached with intramuscular administering after approx. 30 mins. The plasma level quickly decreases within the first 10 minutes after intravenous application. The distribution after parenteral administration takes place very quickly, the distribution volumes amount to 1.7 to 4 l/kg. The plasma protein binding varies between individuals and very strongly from 2 to 40% with age. Atropine sulphate passes through the placenta and is transferred in small quantities to breast milk. The elimination is biphasic with plasma half-lives of 2 – 3 hours or 12 – 38 hours and mainly takes place renally. Approximately 50% are eliminated unchanged, a part is metabolised in the liver (splitting of the ester, demethylation and glucuronidation). Atropine sulphate cannot be dialysed.

5.3 Preclinical safety data

a) Acute toxicity. Also see section "Emergency measures, symptoms and antidote". The lethal dose in adults amounts to approx. 100 mg Atropine, with 10 mg Atropine in children. However, cases of death in children have also been observed following 2 mg Atropine.

b) Chronic toxicity/Sub chronic toxicity. In experiments on animals (rats) the chronic intraperitoneal administration of 80 mg Atropine sulphate/kg body weight caused a reduced weight gain of the test animals as well as degenerative changes to the liver. Hydronephrosis and massive parenchymal degeneration of the kidneys was detected.

c) Mutagenic and tumorigenic potential. There are no indicators of mutagenic and tumorigenic potential.

d) Reproductive toxicity. Observations of 400 mother-child pairs, who were treated during the first trimester of pregnancy with atropine, showed no evidence of embryo toxic potential. The subcutaneous application of 50 mg Atropine sulphate/kg body weight in animal experimentation (mouse) led to embryonal skeletal deformities.

6. Pharmaceutical Particulars

6.1 List of excipients

Lactose monohydrate, potato starch, talcum, gelatin, magnesium stearate

6.2 Incompatibilities

Dysurgal® 0,5 mg should not be prescribed together with adrenalin or noradrenaline.

6.3 Shelf life

The shelf life of Dysurgal® 0,5 is 3 years.
This medication should no longer be used after the expiry date.

6.4 Special precautions for storage

Like all medications, Dysurgal® 0,5 mg should be kept out of reach of children.

6.5 Nature and content of container

Original packets with 20 Tablets N 1
Original packets with 50 Tablets N 2
Original packets with 100 Tablets N 3
Hospital packages

6.6 Instructions for use

see 4.2

7. Marketing Authorization Holder

MaxMedic Pharma GmbH
Pasinger Str.
16 82166 Gräfelfing

8. Authorization number

5899.99.99

9. Date of the renewal of marketing authorization

Not applicable, since standard approval according to § 36 AMG

10. Date of revision of text

September 2006

11. Prescription/Pharmacy prescription

Only available on prescription

Central request to:
Rote Liste Service GmbH
FachInfo-Service
Postfach 11 01 71
10831 Berlin