

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

SPASMEND TABLETS

COMPOSITION:

Each tablet contains:

Mephenesin	150 mg
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Paracetamol	500 mg
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Preservative:

Nipastat/salistat (total parabens)	0,1 % <i>m/m</i>
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List of excipients:

Corn starch, croscarmellose sodium, gelatine, green apple colourant, magnesium stearate.

Sugar free.

CATEGORY AND CLASS:

A 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:

SPASMEND combines the analgesic and antipyretic properties of paracetamol with the skeletal muscle relaxant effect of mephenesin.

INDICATIONS:

SPASMEND tablets are indicated for generalised pain associated with tension.

CONTRAINDICATIONS:

Impaired kidney and liver function. Hypersensitivity to paracetamol or mephenesin.

WARNINGS AND SPECIAL PRECAUTIONS:

Do not use continuously for more than 10 days without consulting a doctor.

Dosage in excess of those recommended may cause severe liver damage.

Paracetamol should be given with care to patients with impaired renal or hepatic function.

Mephenesin may cause drowsiness; patients so affected should not drive or operate machinery (see **INTERACTIONS**).

INTERACTIONS:

Mephenesin may enhance the effects of barbiturates and opioids.

HUMAN REPRODUCTION:

Safety during pregnancy and lactation has not been proved.

DOSAGE AND DIRECTIONS FOR USE:

Adults: One or two tablets every four hours. The maximum dosage is eight tablets per day

Consult a doctor if no relief is obtained with the recommended dosage.

SIDE EFFECTS:

Paracetamol: Sensitivity reactions resulting in reversible skin rash or blood disorders, neutropenia, pancytopenia, leucopenia, may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.

Mephenesin: Mephenesin may produce lassitude, anorexia, nausea and vomiting. Allergic reactions may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS

TREATMENT:

In the event of an overdose, consult a doctor immediately or take the person to the nearest hospital immediately, as specialised treatment is essential as soon as possible.

The latest information regarding the treatment of overdose can be obtained from the nearest poison information centre.

Paracetamol overdose: Prompt treatment is essential. Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain.

Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. Hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop. Cardiac arrhythmias have been reported. Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdose. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and non-specific myocardial depression have also occurred.

Any person who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible.

Mephesisin: Overdose may produce nystagmus, blurred vision and motor inco-ordination; in gross overdose there may be hypotonia, a fall in blood pressure and respiratory paralysis. Treatment is symptomatic and supportive.

IDENTIFICATION:

Light green, round, flat, bisected tablets.

PRESENTATION:

Blister packs of 24, 48 or 100 tablets.

100 tablets packed in a white polypropylene securitainer.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 30 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

B 1490 (Act 101/1965)

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

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