PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S2**

1. NAME OF THE MEDICINE

SPASMEND TABLETS

Strength

Mephenesin	150 mg
Paracetamol	500 mg

Pharmaceutical form

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each SPASMEND tablet contains:

Mephenesin	150 mg
Paracetamol	500 mg

Sugar free

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Light green, round, flat bevelled edge tablets scored on one side.

Contains pregelatinised starch as a diluent.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For generalised and symptomatic pain associated with tension.

4.2 Posology and method of administration

Posology

Adults (18 years and older): Take one or two tablets orally every four hours. The maximum dosage is eight tablets per day, for 10 days.

Consult a doctor if no relief is obtained with the recommended dosage. Do not use continuously for more than 10 days without consulting a doctor.

DO NOT EXCEED THE RECOMMENDED DOSE

The safety and efficacy of SPASMEND in children aged below 18 years old has not yet been established.

4.3. Contraindications:

- Impaired kidney and liver function.
- Hypersensitivity to paracetamol or mephenesin or to any of the other excipients in SPASMEND TABLETS.

4.4 Special warnings and precautions for use:

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

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 enhance the effects of barbiturates and opioids (see **Interaction with other medicines and other forms of interactions**).

Mephenesin may cause drowsiness; patients that are affected should not drive or operate machinery (see **Effects on ability to drive and use machines**).

4.5 Interaction with other medicines and other forms of interactions

Mephenesin may enhance the effects of barbiturates and opioids (see **Special warnings and precautions for use**).

4.6. Fertility, pregnancy and lactation

Safety affecting fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Mephenesin may cause drowsiness; patients that are affected should not drive or operate machinery.

4.8 Undesirable effects

Frequency	**System Organ Class**	**Undesirable effects**
Frequency Unknown	Blood and the lymphatic system disorders	Anaemia.
	Cardiac disorders	Tachycardia, low blood pressure.
	Gastrointestinal disorders	Anorexia, nausea and vomiting, abdominal pain.
	General disorders and administration site conditions	Lassitude, drowsiness, fever.

	Immune system disorders	Sensitive allergic reactions, skin rash, blood disorders such as neutropenia, pancytopenia, leucopenia.
	Skin and subcutaneous tissue disorders	Erythematous or urticarial skin rash, sometimes accompanied by fever and mucosal lesions, facial edema, pruritus, dyspnea, general edema without skin eruption, cutaneous eruptions like contact dermatitis and erythema multiform like eruptions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form",** found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

One may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

4.9 Overdose

Paracetamol:

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage:

Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose, endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given **intravenously** over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four hours, and then

100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children**.

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.

Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”. Prothrombin index correlates best with survival.

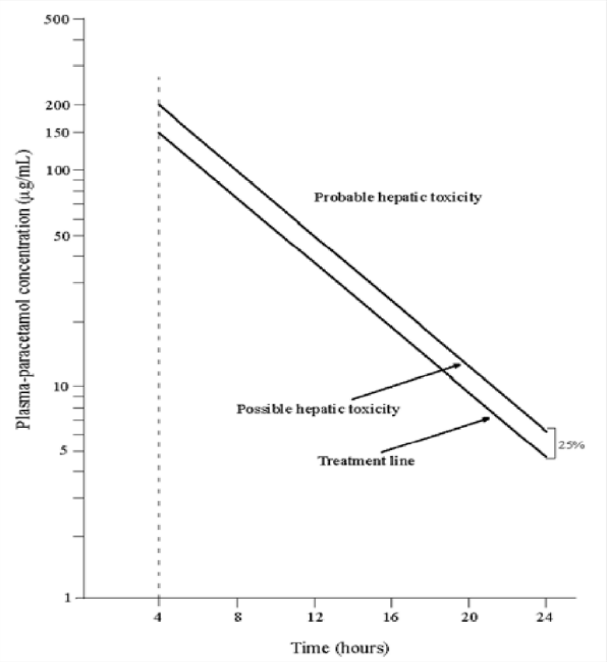

Figure 1. A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

Mephenesin:

Overdosage may produce nystagmus, blurred vision and motor in-coordination; in gross overdosage there may be hypotonia, a fall in blood pressure and respiratory paralysis. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 2.8 Analgesic combinations.

Mechanism of action

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium, colloidal anhydrous silica, pregelatinised starch, Colour Green Apple Deep F1620@, magnesium stearate, maize starch.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

3x8's (24's), 6x8's (48's) and 5x20's (100's) blister packs using PVC film & printed aluminium foil.

100 tablets packed in a white cylindrical HDPE screw type container with induction sealing, screw cap and silica gel.

Not all pack sizes indicated are necessarily marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER:

B 1490 (Act 101/1965)

9.DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 September 1969

10. DATE OF REVISION OF THE TEXT:

14 October 2022

Botswana: S3 B9323375
Namibia: NS1 14/2.9/0412

Approval date: 14/10/2022

Bindia Naidoo Digitally signed by Bindia Naidoo