**Proposed professional information for DOAN'S BACKACHE PILLS**

## SCHEDULING STATUS

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## 1. NAME OF THE MEDICINE

DOAN'S BACKACHE PILLS

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

| | |
|---|---|
| Paracetamol | 97,19 mg |
| Sodium salicylate | 48,59 mg |
| Buchu powder extract | 32,40 mg |

Sugar free.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film coated tablets.

Brownish-grey, film coated tablets.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Treatment of pain and inflammation in the muscles, joints and/or back.

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## 4.2 Posology and method of administration

***Posology:***

*Adults and children (12 years and older):*

**DO NOT EXCEED THE RECOMMENDED DOSE.**

Take two (2) tablets four (4) times a day after a meal. The dose can be increased to three (3) tablets four (4) times a day if necessary, to manage the pain.

Treatment duration should be as short as possible. The duration of treatment can range from a few days to a week. DOAN'S BACKACHE PILLS should not be taken for more than 10 days unless advised by a healthcare practitioner.

*Paediatric population:*

The safety and efficacy of DOAN'S BACKACHE PILLS in children younger than 12 years have not been established. No data available. Its use is therefore not recommended.

***Method of administration:***

Orally.

DOAN'S BACKACHE PILLS should be taken after a meal with enough fluid (preferably water).

To ease swallowing, tablets may be broken in parts or crushed before being swallowed with fluid.

## 4.3 Contraindications

- Hypersensitivity to paracetamol, sodium salicylate, buchu powder extract or to any of the excipients listed in section 6.1.
- Caution should be observed in patients with impaired renal or liver function (see section 4.4).

## 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.**

***Liver impairment***

DOAN'S BACKACHE PILLS should be used with caution in patients with liver impairment.

Dosages in excess of those recommended may cause severe liver damage (see section 4.2).

***Renal impairment***

DOAN'S BACKACHE PILLS should be used with caution in patients with renal impairment.

***Surgical procedures***

DOAN'S BACKACHE PILLS should be stopped several days before surgical procedures as it may prolong bleeding time.

## 4.5 Interaction with other medicinal products and other forms of interaction

The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic medicines or medicines that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by medicines such as metoclopramide. Excretion may be affected, and plasma concentrations altered when given with probenecid. Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

DOAN'S BACKACHE PILLS should not be taken with other medicines that contains aspirin.

## 4.6 Fertility, pregnancy and lactation

The safety of DOAN'S BACKACHE PILLS during pregnancy and lactation has not been established. DOAN'S BACKACHE PILLS should not be taken during pregnancy and lactation.

***Fertility***

There is no fertility data available.

## 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive a vehicle and use machines have been performed.

## 4.8 Undesirable effects

***Summary of the safety profile***

The most common side effects are nausea, vomiting and dyspepsia.

**Blood and lymphatic system disorders:**

*Frequency unknown:* Thrombocytopenia, leucopenia, pancytopenia, neutropenia, agranulocytosis.

**Immune system disorders:**

*Less frequent:* Hypersensitivity.

**Gastrointestinal disorders:**

*Frequent:* Nausea, vomiting, dyspepsia.

**Hepato-biliary disorders:**

*Frequency unknown:* Hepatotoxicity.

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**Skin and subcutaneous tissue disorders:**

*Frequency unknown:* Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis.

***Reporting of suspected adverse reactions***

Reporting suspected adverse reactions after authorisation of DOAN'S BACKACHE PILLS is important. It allows continued monitoring of the benefit/risk balance of DOAN'S BACKACHE PILLS. Health care providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (SAHPRA) via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

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

Suspected adverse reactions can also be reported directly to Mentholatum SA at https://www.mentholatum.co.za.

## 4.9 Overdose

**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 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, acquired immune deficiency syndrome (AIDS), malnutrition, and with the use of medicines that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

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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 dysrhythmias have been reported.

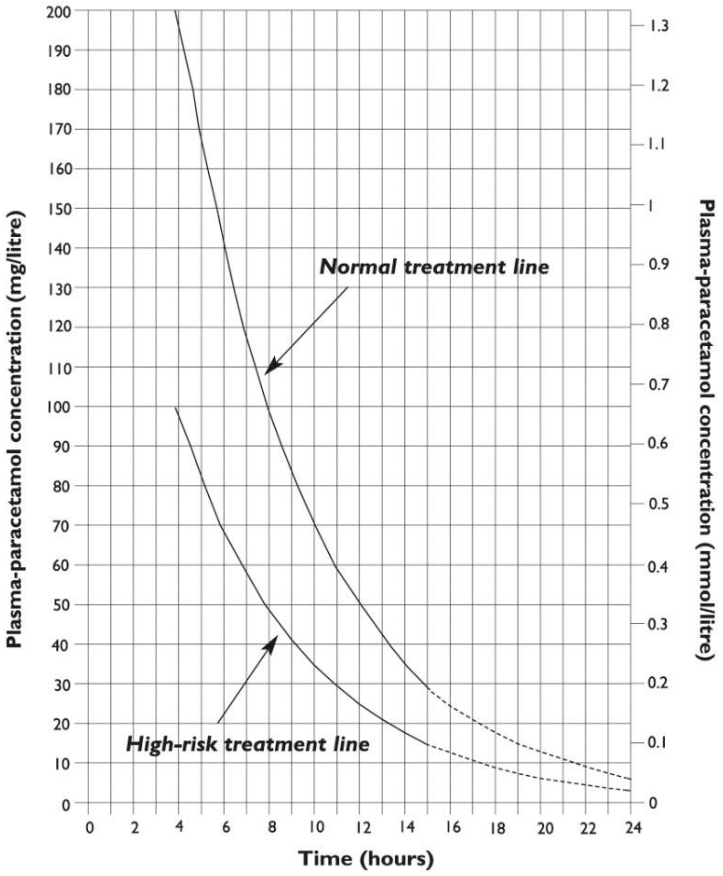
***Treatment for paracetamol overdosage:***

Although evidence is limited it is recommended that any adult person who has ingested 5 – 10 g 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 stuporous 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. Monitor all patients with significant ingestions for at least ninety-six hours.

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## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Category and class: A 2.7 Antipyretics or antipyretic and anti-inflammatory analgesics**

***Paracetamol***

Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties and weak anti-inflammatory activity.

***Sodium salicylate***

Sodium salicylate is a salicylic acid derivative that has analgesic, anti-inflammatory and antipyretic properties.

***Buchu powder extract***

Buchu powder extract has anti-inflammatory properties.

### 5.2 Pharmacokinetic properties

***Paracetamol***

Paracetamol is readily absorbed from the gastrointestinal tract and peak plasma concentrations occur about 10 to 60 minutes after oral doses.

Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

The elimination half-life of paracetamol varies from about 1 to 3 hours.

Paracetamol is metabolised mainly in the liver and excreted in the urine. Less than 5 % is excreted as unchanged paracetamol.

***Sodium salicylate***

Sodium salicylate is rapidly absorbed from the gastrointestinal tract after oral administration.

Salicylate is extensively bound to plasma proteins and is rapidly distributed to all body parts.

Salicylate appears in breast milk and crosses the placenta.

Salicylate is mainly eliminated by hepatic metabolism.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

***Tablet core***

Acid hydrolysed starch (1500)

Magnesium stearate

Povidone

Stearic acid

Talcum

***Tablet coating***

*Flexicoat Grey:*

Polyethylene glycol

Polyvinyl alcohol

Sicovit Black (E172)

Sicovit Red (E172)

Sicovit Yellow (E172)

Talcum

Titanium dioxide (E171)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years.

### 6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

Keep the tablets in the original container until required for use.

### 6.5 Nature and contents of container

White, PP securitainer with white, LDPE securitainer closure with an orange and black label printed on the securitainer. Each securitainer contains 18, 48 or 100 tablets.

Polypaper sachet (printed) containing 2 tablets, packed on a printed cardboard carton. Each cardboard carton contains 48 sachets.

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Mentholatum SA (Pty) Ltd

1st Floor, Silverberg Terrace

Steenberg Office Park

Silverwood Close

Tokai 7945

## 8. REGISTRATION NUMBER

B 957 (Act 101 of 1965)

Signed: _____

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

December 1975

## 10. DATE OF REVISION OF THE TEXT

Signed: 