1.3.1.1 PROFESSIONAL INFORMATION - CLEAN

SCHEDULING STATUS

S0 50 ml and 100 ml

S1 200 ml, 500 ml and 2,5 l

1. NAME OF MEDICINE

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE

PAINBLOK SYRUP

Paracetamol 120 mg / 5 ml

Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE

Each 5 ml contains: Paracetamol 120,0 mg

Preservative: Methyl Hydroxybenzoate 0,12 % m/v

Sugar free

Contains sweeteners sodium cyclamate 20 mg / 5ml and sodium saccharin 2 mg / 5 ml

For a full list of excipients, see section 6.1

PAINBLOK SYRUP

Each 5 ml contains: Paracetamol 120,0 mg

Preservatives: Methylparaben 0,09 % m/v

Propylparaben 0,01 % m/v

Contains ethanol (96,5 %) 0,514 ml / 5 ml equivalent to ethanol 10 % v/v

Contains no tartrazine.

Contains sugar: liquid glucose 2,497 g / 5 ml and sucrose 0.832 g / 5 ml

Contains sweetener: sodium saccharin 0,01 g / 5 ml

Contains propylene glycol 0,57 ml / 5 ml equivalent to 11 % v/v.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: A clear, dark pink syrup with an odour and taste of Raspberry.

PAINBLOK SYRUP: A sweet caramel/ peppermint flavoured green syrup

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the symptomatic relief of mild to moderate pain and fever.

4.2. Posology and method of administration

DO NOT EXCEED THE RECOMMENDED DOSE

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE	**PAINBLOK SYRUP**
3-12 months 2,5 to 5 ml 1- 5 years 5 to 10 ml 6- 12 years 10 to 20ml While symptoms persist, the dose may be repeated every 4 hours but not more than 4 doses in 24 hours	2- 4 years 2,5 to 5 ml 5 - 8 years 5 to 10 ml 9- 12 years 10 to 20 ml While symptoms persist, the dose may be repeated every 8 hours but not more than 4 doses in 24 hours

DO NOT USE CONTINUOUSLY FOR MORE THAN 10 DAYS WITHOUT CONSULTING YOUR DOCTOR

Method of administration

Orally

4.3. Contraindications

Hypersensitivity to paracetamol.

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: hypersensitivity to any of the ingredients listed in section 6.1.

PAINBLOK SYRUP: hypersensitivity to any of the ingredients listed in section 6.1.

Severe liver function impairment.

4.4. Special warnings and precautions for use

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE 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 (see section 4.8).

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

Patients suffering from hepatitis or alcoholism, or recovering from any form of liver disease, should not take excessive quantities of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE.

Do not use continuously for more than 10 days without consulting your doctor (see section 4.2).

Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

Paracetamol should be taken / given with care to patients with impaired kidney or liver function.

Use with caution in renal disease, alcohol dependence, chronic malnutrition or dehydration.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS) / Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR, treatment with GULF PARACETAMOL must immediately be discontinued and appropriate treatment instituted (see section 4.8).

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

Excipients with known effect

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE

- Contains methyl- and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed) (see section 4.8).

PAINBLOK SYRUP

- Contains methyl hydroxybenzoate: May cause allergic reactions (possibly delayed) (see section 4.8).
- Contains glucose 2,497 g and sucrose 0,832 g per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- Contains propylene glycol 0,57 ml / 5 ml equivalent to 11 % v/v.

  If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

  If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine (refer section 4.6).

  If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

  Propylene glycol in this medicine at a dosage of 20 ml four times daily in patients of 10 kg weight can have the same effects as drinking alcohol and increase the likelihood of side effects. Use this medicine at this dosage only if recommended by a doctor. Your doctor may carry out extra checks while you are taking this medicine.

4.5. Interaction with other medicines and other forms of interaction

- Concomitant use of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE with hepatotoxic and enzyme inducing medicines may increase the risk of hepatotoxicity with a possible decrease in therapeutic effects of paracetamol.
- Metoclopramide: absorption of paracetamol may be increased.
- Cholestyramine: absorption of paracetamol is reduced if given within one hour of cholestyramine.
- Salicylates: prolonged concurrent use with paracetamol increases the risk of adverse renal effects.
- Warfarin and anticoagulants: concurrent, regular daily use of high-dose administration of paracetamol

may enhance the anticoagulant effect with an increased risk of bleeding – use with caution. Increased monitoring of anticoagulant therapy may be appropriate for those taking paracetamol regularly.

- Antiepileptics: plasma-paracetamol concentrations considered an indication for antidote treatment should be halved in patients receiving enzyme inducing drugs such as carbamazepine, phenobarbital, phenytoin, or primidone.
- Probenecid: can decrease paracetamol clearance and increase its plasma half-life.
- Antibacterials: plasma-paracetamol concentrations considered as an indication for antidote treatment should be halved in patients receiving enzyme inducing drugs such as rifampicin. Severe hepatotoxicilty at therapeutic doses or moderate overdoses of paracetamol has been reported in patients receiving isoniazid, alone or with other medicines for tuberculosis.
- Antivirals: paracetamol enhances the antiviral effect of interferon alfa.

4.6. Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and lactation have not been established.

If you are pregnant or breast-feeding, do not take PAINBLOK SYRUP unless recommended by your doctor (refer section 4.4).

No data known on fertility.

4.7. Effects on ability to drive and use machines

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE and PAINBLOK SYRUP has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Blood and lymphatic system disorders

Less frequent: neutropenia, leucopenia or pancytopenia, agranulocytosis, thrombocytopenia and anaemia.

Metabolism and nutrition disorders

Frequency unknown: pyroglutamic aciduria (5-oxoprolinuria) and high-anion gap metabolic acidosis.

Ear and labyrinth disorders

Frequency unknown: Hearing loss.

Cardiac disorders

Frequency unknown: hypertension

Renal and urinary disorders:

Less frequent: Renal colic, renal failure and sterile pyuria.

Frequency unknown: nephropathy

Hepatobiliary disorders:

Less frequent: Hepatitis.

Gastrointestinal disorders:

Less frequent: Pancreatitis.

Frequency unknown: Nausea and vomiting.

Skin and subcutaneous tissue disorders

Less frequent: Hypersensitivity reactions resulting in reversible skin rash may occur. The rash is usually ertythematous or urticarial, but sometimes more serious and may accompanied by fever and mucosal lesions. More mild rashes and other hypersensitivity reactions also occur occasionally.

Serious cutaneous adverse reactions (SCAR) include toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS) / Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) (see section 4.4).

General disorders and administrative site conditions

Hypersensitivity reactions characterised by urticaria, dyspnoea, and hypotension.

Post-marketing experience

The risk of SCARs is very serious, potentially life-threatening / fatal and appear to be unpredictable.

Undesirable effects due to excipients (see section 4.4)

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE

- Allergic reactions (possibly delayed) due to preservatives.

PAINBLOK SYRUP: Allergic reactions (possibly delayed) due to preservatives.

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

4.9. Overdose

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly. 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, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms (see section 4.8)

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.

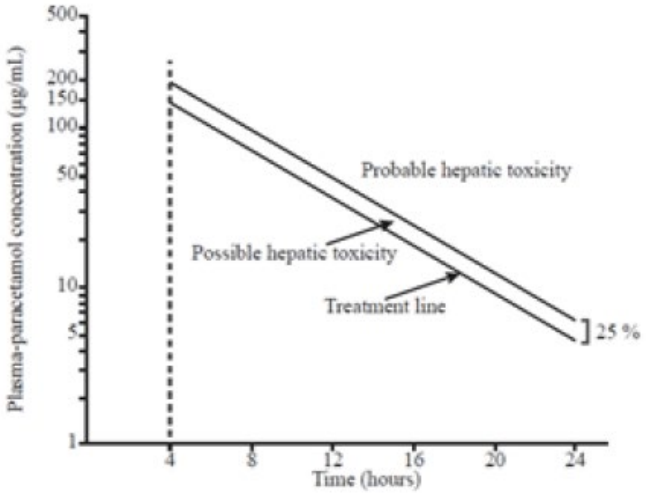
N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken.

IV: An initial dose of 150 mg/kg in 200 ml injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml over the next 16 hours. **The volume of intravenous fluids should be modified for children**.

Orally: Although the oral formulation is not the treatment of choice 140 mg/kg as a 5% solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours, unless high, may be misleading. Patients at risk of liver

damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 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.



Source: Martindale: The Complete Drug Reference -37th Edition.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological class

A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics.

ATC code: N02BE01

Pharmacological action

Paracetamol has analgesic and antipyretic actions.

5.2. Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring after 0,5 to 1 hour after oral administration.

Once absorbed, the plasma half-life of paracetamol is about 2 hours.

It is distributed into most body tissues. Plasma-protein binding varies. It crosses the placenta and is presented in breast milk.

Paracetamol is metabolised predominantly in the liver conjugation with glucuronic acid (about 60 %), sulphuric acid (about 35 %) and cysteine (about 3 %) and excreted in the urine primarily as inactive conjugated metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: Methyl hydroxybenzoate, povidone 25 oral grade, glycerol, Raspberry flavour 1220702, raspberry S colour, sodium cyclamate, sodium saccharin, purified water

PAINBLOK SYRUP:

Propylene glycol, ethanol 96,5%, chloroform, liquid glucose, sucrose, methyl hydroxybenzoate, propyl hydroxybenzoate, sodium saccharin, Deep Apple Green F1620 [CI 47005,44090,42090,15985,16255], Essence of Caramel, peppermint oil, purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months if stored in a well-closed container at or below 25°C, protect from light.

Exposure to air should be kept to a minimum.

6.4. Special precautions for storage

None.

6.5. Nature and contents of container

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE:

50 ml and 100 ml glass bottle in a unit carton.

Plastic bottles with 50 ml, 100 ml, 200 ml and 500 ml.

White HDPE bottles with 50 ml and 100 ml with LDPE cap.

HDPE Polycans with 2,5 L.

PAINBLOK SYRUP:

100 ml glass bottle in a unit carton.

Plastic bottles with 50 ml, 100 ml, 200 ml and 500 ml.

HDPE Polycans with 2,5 L.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

GULF DRUG COMPANY (PTY) LTD.

22 BURNSIDE DRIVE

OLD MILL INDUSTRIAL PARK

MOUNT EDGECOMBE

4300

8. REGISTRATION NUMBER

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: 29/2.7/0208

PAINBLOK SYRUP: B 1454 (Act 101 of 1965)

9. DATE OF FIRST AUTHORISATION

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: 28 March 1996

PAINBLOK SYRUP: 16 March 1992

10. DATE OF REVISION OF THE TEXT

23 September 2023