PATIENT INFORMATION LEAFLET

Scheduling Status
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PAINBLOK SYRUP ALCOHOL AND SUGAR FREE
PAINBLOK SYRUP
120 mg / 5 ml syrup
Paracetamol

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: Contains sorbitol 0,750 mg / 5ml. Contains sweetener: Sodium saccharin 2 mg / 5 ml and sodium cyclamate 20 mg / 5ml.
PAINBLOK SYRUP: 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

Read the entire leaflet carefully because it contains important information for you
PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet
1. What PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP is and what it is used for
2. What you need to know before you take PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
3. How to take PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
4. Possible side effects
5. How to store PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
6. Contents of the pack and other information

1. What PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP is and what it is used for
PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP belongs to a group of medicines known as analgesics and antipyretics.
This medicine is used for the relief of mild to moderate pain and fever.

2. What you need to know before you take PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP:
Do not take PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
- If you are sensitive (allergic) to paracetamol or ever had a harmful reaction to paracetamol or any of the other ingredients of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP (listed in section 6).
- If you have severe liver function impairment.

Do not use continuously for more than 10 days without consulting your doctor.
Dosages in excess of those recommended may cause severe liver damage.
Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Consult your doctor if no relief is obtained with the recommended dosage.
If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

If you are pregnant or breastfeeding your baby while taking this medicine consult your doctor, pharmacist or other health care professional for advice.

Severe skin reactions have been reported in some patients taking paracetamol. If you develop any skin reactions stop taking PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP and consult your doctor of pharmacist or go to your nearest hospital.

Other medicines and PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.

If PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP is taken at the same time as the medication listed below, unwanted side effects can be experienced:
- Hepatotoxic medicines (e.g. isoniazid): Increased risk of liver toxicity.
- Enzyme-inducing medicines (e.g. carbamazepine; rifampicin): Increased risk of liver toxicity and possible decreased effects of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP.
- Metoclopramide (used for nausea and vomiting): Increased absorption of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP.
- Probenecid (used to increase uric acid excretion): Decreased clearance and increased half-life of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP.
- Cholestyramine (used to lower high cholesterol levels): Reduced absorption of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP, if taken within one hour of cholestyramine.
- Salicylates (e.g. aspirin): Prolonged use can increase the risk of adverse kidney effects.
- Antibiotics (e.g. isoniazid – chronic use): Increased risk of liver damage.
- Antivirals: Paracetamol enhances the antiviral effect of interferon alfa.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving or using machines
It is not always possible to predict what effect PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP will have on you. Do not drive or use machines until you are aware of the effects it has on you.

- Sorbitol 750 mg / 5 ml which is equivalent to 15 % *w/v.* Sorbitol is a source of fructose. Patients with the rare hereditary fructose intolerance (HFI) condition should not take / be given PAINBLOK SYRUP ALCOHOL AND SUGAR FREE. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- Methyl- and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

PAINBLOK SYRUP contains:
- Methyl hydroxybenzoate: May cause allergic reactions (possibly delayed).
- Glucose and sucrose. This should be taken into account in patients with high blood sugar. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take this medicine.
- Propylene glycol. 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 breastfeeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
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.

3. How to take PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
Always take PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
Doses to be taken orally.

The usual doses are

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

If you take more PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP than you should
In the event of over dosage or suspected overdose and even if there are no symptoms, immediately consult your doctor or pharmacist. If neither is available, immediately rush the patient to the nearest hospital or poison control centre.

4. Possible side effects
PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP can have side effects.
Skin rashes and other allergic reactions may occur.
Serious skin reactions (SCAR) which are potentially life threatening or fatal have been reported.
Leucopenia (decrease in leucocytes), neutropenia (decrease in neutrophils) and pancytopenia may occur.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist, or nurse You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP

5. How to store PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP
Store all medicines out of reach of children.
Store in a cool, dry place, below room temperature (25 ºC).
Keep the container tightly closed.
Protect from light.
Do not store in a bathroom.
Do not use after the expiry date stated on the label/carton or container.
Return all unused or expired medicines to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of pack and other information
The active substance is paracetamol 120 mg / 5 ml.

PAINBLOK SYRUP ALCOHOL AND SUGAR FREE
The preservative is methyl hydroxybenzoate 0,12 % *m/v.*
The other ingredients are methyl hydroxybenzoate, povidone 25 oral grade, sorbitol solution, glycerol, Essence of Caramel, Deep Apple Green F1620 [CI 47005, 44090,42090,15985,16255], peppermint oil, sodium cyclamate, sodium saccharin, purified water.

PAINBLOK SYRUP
The preservatives are methyl hydroxybenzoate 0,09 % *m/v* and propyl hydroxybenzoate 0,01 % *m/v.*
The other ingredients are 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.

What PAINBLOK SYRUP ALCOHOL AND SUGAR FREE or PAINBLOK SYRUP looks like and contents of the pack
PAINBLOK SYRUP ALCOHOL AND SUGAR FREE: A clear, green coloured liquid with a characteristic caramel/ peppermint odour and taste.
- 50 ml and 100 ml glass bottle in a unit carton
- Plastic bottles with 50 ml and 100 ml

PAINBLOK SYRUP: A sweet caramel/ peppermint flavoured green syrup
- 100 ml glass bottle in a unit carton
- Plastic bottles with 50 ml and 100 ml

Holder of the Certificate of Registration
Gulf Drug Company (Pty) Ltd
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Mount Edgecombe, 4300

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