Read this entire leaflet carefully because it contains important information. This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use STOPAYNE® SYRUP BLACKCURRANT carefully to get the best results from it. Keep this leaflet, as you may need to read it again. Ask your pharmacist if you need more information or advice. You must see a doctor if you or your child's symptoms worsen or do not improve while taking this medicine.

SCHEDULING STATUS: **S2**

PROPRIETARY NAME: STOPAYNE® SYRUP BLACKCURRANT
(AND DOSAGE FORM) (SYRUP)

WHAT STOPAYNE® SYRUP BLACKCURRANT CONTAINS:

The active ingredients in **STOPAYNE® SYRUP BLACKCURRANT** are:

Codeine phosphate	5 mg
Promethazine hydrochloride	6, 5 mg
Paracetamol	120 mg

The other ingredients are: polyvinylpyrrolidone, glycerol, xanthan gum, propylene glycol, methyl paraben, sorbitol 70 % solution, citric acid anhydrous, disodium edetate, sodium metabisulphite, saccharin sodium and methyl hydroxybenzoate, liquid glucose, blackcurrant flavour, colour raspberry red, colour blackcurrant.

WHAT STOPAYNE® SYRUP BLACKCURRANT IS USED FOR? :

STOPAYNE® SYRUP BLACKCURRANT is indicated for the relief of mild to moderate pain associated with fever in children over the age of 2 years.

BEFORE YOU TAKE STOPAYNE® SYRUP BLACKCURRANT:

Do not take STOPAYNE® SYRUP BLACKCURRANT if you or your child:

- are hypersensitive (allergic) to codeine phosphate, promethazine hydrochloride, paracetamol or any of the other ingredients of **STOPAYNE® SYRUP BLACKCURRANT**.
- have **serious** problems with your liver function.
- are taking monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

STOPAYNE SYRUP® BLACKCURRANT should not be given to children under 2 years of age.

Take special care with STOPAYNE SYRUP® BLACKCURRANT:

- If you or your child have a history of liver disease or of heavy alcohol consumption, as this can worsen the adverse effects of **STOPAYNE SYRUP® BLACKCURRANT** on the liver.
- Do not use continuously for longer than ten days without consulting your doctor.

Pregnancy and Breastfeeding: Safety in pregnancy and lactation has not been established.

Taking other medicines with STOPAYNE SYRUP® BLACKCURRANT:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of STOPAYNE SYRUP® BLACKCURRANT with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

When you are taking **STOPAYNE SYRUP® BLACKCURRANT**, you must tell your doctor if you are taking any of the following:

- Alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants and phenothiazines worsen the depressant effects
- The effects of medicines that cause blurred vision, confusion, constipation, dry mouth, light-headedness, difficulty passing urine and loss of bladder control may be increased.

- Monoamine oxidase inhibitors may increase the following side effects of this medicine: blurred vision, confusion, constipation, dry mouth, light-headedness, difficulty passing urine and loss of bladder control.

- The warning signs of damage caused by medicines that are harmful to the ear may be masked.
- Antidiarrhoeals (used for diarrhoea)
- Metoclopramide (alleviates nausea & vomiting)
- Probenecid (aids with excretion of acid in urine)
- Antidiabetic agents (counteracting diabetes)
- Anticoagulants (substance to stop blood from clotting)
- Any other medicine(s) including medicines used for respiratory, inflammatory, heart, blood, blood clotting, bone, cancer and mental conditions.

HOW TO TAKE STOPAYNE SYRUP® BLACKCURRANT:

Do not share medicines prescribed for your child with other persons.
Personally administer the medicine to your child according to the following dosage recommendations; You should check with your doctor or pharmacist if you are unsure.

Children from 2 to 5 years: 5 ml (One medicine measureful)
Children over 5 years: 5 - 10 ml (One to two medicine measureful)

If you have the impression that the effect of **STOPAYNE SYRUP® BLACKCURRANT** is too strong or too weak, talk to you doctor or pharmacist.

If you or your child takes more STOPAYNE SYRUP® BLACKCURRANT than you should:

In the event of overdosage, ask your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you or your child missed taking a dose of STOPAYNE SYRUP® BLACKCURRANT:

Do not take a double dose to make up for forgotten individual doses.

SIDE EFFECTS:

STOPAYNE SYRUP® BLACKCURRANT can have side effects.

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 healthcare professional for advice.

Check with your doctor immediately if any of the following side effects occur:

Less Frequent: skin rash, restlessness and confusion, miosis (a contraction of the pupil of the eye), bradycardia (slowness of the heart rate), palpitations (abnormal awareness of one's heart beat), dizzy spell on standing up, difficulty breathing, nausea, vomiting, dry mouth, pruritus (an intense feeling of itchiness), sweating, facial flushing, anorexia, excitation in children, irritability, nightmares, blurred vision and photosensitivity.

Frequent: drowsiness, constipation and sedation.

The following side effects have been reported but their frequencies are unknown: blood disorders, skin rash, change of mood, muscle rigidity, convulsions, raised intracranial pressure, deepening coma, shock hypothermia (low body temperature), jaundice (yellowing of the whites of the eyes, skin, and mucous membranes), blood disorders, allergic reaction, *increased* appetite, muscular weakness, headache, inco-ordination, nausea, vomiting, diarrhoea or constipation.

- Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
- Codeine should be given with caution to patients with thyroid disease.
- Promethazine must be used with caution in conditions such as glaucoma (increase in inner eye pressure) and urinary tract blockage. Large doses may precipitate fits in epileptics.
- Serious life-threatening cases of abnormally slow and/or shallow breathing have been reported with promethazine use in paediatric patients less than 2 years of age.

STORAGE AND DISPOSING OF STOPAYNE SYRUP® BLACKCURRANT:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store above 25°C. Store in the original packaging or container. Keep the container tightly closed. Protect from light and moisture. Do not store in bathrooms. Do not use after the expiry date stated on the label. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

PRESENTATION:

Amber glass bottles of 100 ml.

IDENTIFICATION:

Mauve syrup, with a blackcurrant flavour.

REGISTRATION NUMBER:

B/2.8/867

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

Adcock Ingram Limited
1 New Road, Erand Gardens,
Midrand, 1685
Private Bag X69, Bryanston 2021
www.adcock.com

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

To be allocated.