Patient Information Leaflet

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

PAINAGON®SYRUP

Paracetamol 120 mg; codeine phosphate 5 mg,

promethazine 6,5 mg

Contains sugar:

Sucrose: 1,825 g/ 5ml

Liquid glucose 2g/ 5ml

Invert syrup 600mg/5ml

Contains sweetener:

Saccharin sodium:1,5mg/ 5ml

Sodium cyclamate 30 mg/ 5ml

Read all of this leaflet carefully because it contains important Information for you

PAINAGON®SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PAINAGON®SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PAINAGON®SYRUP with any other person
- Ask your healthcare provider or pharmacist if you need more information or advise.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What painagon®syrup is and what it is used for

PAINAGON®SYRUP contains the active substances paracetamol; codeine phosphate and promethazine.

PAINAGON®SYRUP is used for the relief of mild to moderate pain, associated with fever.

2. What you need to know before you take PAINAGON®SYRUP

Do not take PAINAGON®SYRUP:

- If you are hypersensitive (allergic) to paracetamol; codeine phosphate or promethazine or any of the other ingredients of PAINAGON®SYRUP listed in section 6.

  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are sensitive to one antihistamine and may be sensitive to others.
- If you are a patients with severe liver or kidney complications.
- If you are a patients with obstructive airway disease, respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, and after operations on the biliary tract. ·
- If you are an alcoholic
- If you are having an epileptic fit
- If you have head injuries and conditions in which intracranial pressure is raised
- If you under 2 years of age.

- If you are pregnant and breastfeeding
- If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment
- If you having an asthma attack

Warnings and precautions

Take special care with PAINAGON®SYRUP :

- If you are using alcohol, or if you are taking other medicines such as sedatives, tranquilisers or sleeping tablets, as it may lead to drowsiness and impaired concentration. You should take care not to drive or operate machinery, particularly at the start of treatment, as this may lead to accidents (see **driving and using machines**)
- If a patient does not respond, or you are using for more than 10 days consult a doctor.
- If you have abnormal skin discolouration or eye changes
- f you taking doses in excess of the recommended dose as this may cause liver damage
- If you are exceeding the prescribed dose with prolong and continuous use as this may lead to dependency and addiction
- If you have had any past or present liver or kidney disease
- If you have obstructive bowel disorder
- If you have an underactive thyroid
- If you have muscle disorders causing weakness of the muscles
- If you have increased pressure in the eye (glaucoma)
- In patients with urinary retention
- If you have any allergies
- If you are taking or plan to take any medicine, even those you get without a prescription or traditional medicines

- If you suffer from life threatening skin reactions such as Stevens- Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

- If you develop a red, scaly widespread rash with bumps under the skin and/or blisters mainly localized on the skin folds, trunk,and upper extremities accompanied by fever at the start of treatment (acute generalized exanthematous pustulosis).
- If you develop a skin rash, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- If you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching

Other medicines and PAINAGON®SYRUP

Always tell your healthcare provider if you or your child is taking any other medicine (this includes all complementary or traditional medicines

Care should be taken if concomitantly taking with:

- Nervous system depressants such as alcohol, barbiturates, hypnotics (causes sleep), narcotic analgesics (dependence producing substances used for the relief of pain), sedatives (for calming) and tranquillisers (medicines used for calming nerves) and
- anticholinergic medicines (a substance used to stop the release of certain nerve impulses involving acetylcholine),
- tricyclic antidepressants and phenothiazines as their effects may be enhanced by promethazine
- Antidepressants such as Monoamine-oxidase inhibitors (MAOIs) will potentiate both the drowsiness effect and the anticholinergic effects of promethazine, therefore, PAINAGON®SYRUP should not be taken concurrently with patients taking MAOIs or within 14 days of stopping therapy with MAOIs.
- The effects of medicines with anticholinergic activity such as tricyclic antidepressants or phenothiazine will be potentiated.
- Ototoxic medicines (medicines that causes damage to the ear) may be masked.

Pregnancy, breastfeeding and fertility:

PAINAGON®SYRUP should not be taken during pregnancy or breastfeeding (see **Do not use PAINAGON®SYRUP).**

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 PAINAGON®SYRUP

Driving and using machines

The use of PAINAGON®SYRUP leads to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol and it is unsafe to drive a vehicle or be in charge of machinery while using this medicine, as impaired decision making could lead to an accident

PAINAGON®SYRUP contain sucrose, liquid glucose, invert syrup

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

PAINAGON®SYRUP contain 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 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

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.

3. How to take PAINAGON®SYRUP :

Taking your medicine:

Do not share medicines prescribed for you with any other person.

Always take PAINAGON® SYRUP exactly as described in this leaflet or as your doctor or

pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose is:

2 to 5 years:

One medicine measures (5 ml) three times a day

CHILDREN: 6 to 12 years:

One to two medicine measure (5 – 10 ml) three times a day.

DO NOT EXCEED THE RECOMMENDED DOSE

Do not use continuously for more than 10 days without

consulting your doctor.

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If you take more PAINAGON®SYRUP than you should:

Treatment is symptomatic and supportive.

You might experience an increase in side effects in the event of taking more PAINAGON®SYRUP than the recommended dosage.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the carton and bottle with you. This is so the doctor knows what you have taken.

If you forget to take PAINAGON®SYRUP :

If you forget to take PAINAGON®SYRUP**,** take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

4. Possible side effects

PAINAGON®SYRUP can have side effects.

Not all side effects reported for PAINAGON®SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effect while taking PAINAGON®SYRUP,

please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking/using PAINAGON®SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital :

- if you get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficult in swallowing or breathing.
- if you could notice an itchy, nettle rash (urticaria). This may mean that you are having an allergic reaction to PAINAGON® SYRUP**.**
- fainting

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to. You or your child may need urgent medical attention or hospitalisation

Tell your doctor if you notice any of the following:

Frequent side effects

- confusion,
- hallucination,
- euphoria (intense excitement and happiness)
- sedation
- drowsiness
- dizziness,
- headaches
- muscular weakness and incoordination
- nausea, vomiting, diarrhoea
- constipation, anorexia or increased appetite
- pain or discomfort below the ribs
- inflammation of the pancreas
- mental weakness or lack of energy
- difficulty in urination

- sweating

Less Frequent Side Effects

- Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).
- Some of the listed side effects may be due to the diarrhoea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and wind.

Frequency unknown side effects:

- neutropenia(abnormal low count of neutrophils a type of white blood cells), pancytopenia(lower than normal number of red and white blood cells) leukopenia(reduction in number of white blood cells), thrombocytopenia (deficiency of platelets in the blood), agranulocytosis (deficiency of granulocytes in the blood),anaemia (defieciency of red cells)
- allergies resulting in skin rash or blood disorder
- confusion,hallucination,euphoria
- ringing in the ear (tinnitus)
- hypotension (low blood pressure)
- inflammation of the liver
- inflammation of the skin
- muscle weakness
- irreversible kidney damage
- physical or mental weariness, lack of energy
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- tingling
- epileptic fits
- blurred vision
- in high doses a slow heart rate followed by fast heart rate

- flushing
- thickened respiratory tract secretions, dryness of the nose, tightness of the chest
- dryness of the mouth, constipation and increased gastric reflux
- jaundice(yellowing of the skin and eyes)
- difficult and painful urination
- sensitisation of the skin to sunlight (photosensitisation)
- allergic dermatitis,
- abuse, restlessness, change in mood
- a build of pressure around the brain
- shrinkage of pupils of the eye
- middle ear imbalance
- raised itchy rash that appears on the skin
- muscle rigity
- sweating
- drop in body temperature
- skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules or peeling of the skin (Toxic Epidermal Necrolysis) and bleeding in the lips, eyes, mouth, nose and genitals (Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome),
- a red, scaly, widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis),

a severe skin reaction known as DRESS syndrome can occur.
Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells),

- Fixed Drug Eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor or 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 PAINAGON® SYRUP.

5. How to store PAINAGON® SYRUP

- Store all medicines out of reach of children
- Store at or below 25 °C.
- Do not freeze
- Store your medicine in the original packaging in order to protect from light.
- Do not use this medicine after the expiry date shown on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6.Contents of the pack and other information

What PAINAGON® SYRUP contains

The active substance is paracetamol, codeine phosphate and promethazine

Alcohol	12,5 % *v/v*
Preservatives	
Methyl Hydroxybenzoate	0,10 % *m/v*
Propyl Hydroxybenzoate	0,01 % *m/v*

The other ingredients are:

Black currant colour LS 1904/18, citric acid anhydrous, essence of black currant No.1,ethanol 96 % *v/v,* invert syrup, liquid glucose, methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, purified water, rasberry red H1227(Cl 14720), saccharin sodium, sodium cyclamate, sucrose, vanilla flavour No.1

WHAT PAINAGON® SYRUP LOOKS LIKE AND CONTENTS OF THE PACK

Mauve to maroon-coloured clear syrup with a distinctive flavour of blackcurrant.

Amber PVC bottles containing 100ml and 500ml of syrup.

Amber glass bottles containing 100ml of syrup.

H.D.P.E containers, containing 2, 5 litre syrup.

Holder Of Certificate Of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

This Leaflet Was Last Revised In

25 August 2023

8. REGISTRATION NUMBER(S)

S/2.8/29(SA)

B 9314915 (Botswana)

NS1 90/2.8/00375 (Namibia) (100 ml, 500 ml, 2,5 L)