1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TENSOPYN PAEDIATRIC SYRUP.

Each 5 ml syrup contains: 150,0 mg paracetamol and 4,0 mg codeine phosphate.

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

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your or your child's symptoms worsen or do not improve after 5 days.

1. WHAT TENSOPYN PAEDIATRIC SYRUP CONTAINS:

Each 5 ml syrup contains:

Paracetamol	150,0 mg
Codeine phosphate	4,0 mg
Preservatives*:*	
Sodium Benzoate	0,1 % m/v
Potassium Sorbate	0,2 % m/v

The other ingredients are:

Propylene glycol, glycerine, macrogol, sodium cyclamate, acesulfame-K, butylated hydroxytoluene, sodium chloride, blackcurrent flavour, cherry flavour, purified water.

Sugar free. Contains sweetener:

Acesulfame-K	7,5 mg
Sodium cyclamate	10 mg

2. WHAT TENSOPYN PAEDIATRIC SYRUP IS USED FOR:

TENSOPYN PAEDIATRIC SYRUP is used for the relief of mild to moderate pain and fever in children 6 months and older.

3. BEFORE YOU ADMINISTER TENSOPYN PAEDIATRIC SYRUP:

Do not give TENSOPYN PAEDIATRIC SYRUP to your child if:

- your child has had an allergic or unusual reaction to any of the ingredients in **TENSOPYN PAEDIATRIC SYRUP**
- your child has an allergy to any of the ingredients in **TENSOPYN PAEDIATRIC SYRUP**
- your child has severe kidney disease
- your child has jaundice or any other liver disease
- if your child is having an asthma attack
- if your child is having difficulty breathing or has excessive bronchial secretion
- if your child has heart failure secondary to chronic lung disease,
- if your child has head injuries
- if your child is younger than 6 months old.
- If your child is receiving monoamine oxidase inhibitors (anti- depressants) or within 10 days of stopping such treatment.

Take special care with TENSOPYN PAEDIATRIC SYRUP if your child is taking other medicines which have calming effects such as medicines containing alcohol or medicines which cause sleepiness or drowsiness as **TENSOPYN PAEDIATRIC SYRUP** may enhance these symptoms. (Refer “Taking other medicines with TENSOPYN PAEDIATRIC SYRUP”)

TENSOPYN PAEDIATRIC SYRUP should be taken with caution by patients with liver problems.

Taking TENSOPYN PAEDIATRIC SYRUP with food and drink:

TENSOPYN PAEDIATRIC SYRUP may be taken without regard for food or drink.

Pregnancy and Breast-feeding:

TENSOPYN PAEDIATRIC SYRUP is not recommended in pregnancy and lactation.

Paracetamol crosses the placenta and is presented in breast milk.

Driving and using machinery:

TENSOPYN PAEDIATRIC SYRUP is indicated for use by children. As **TENSOPYN PAEDIATRIC SYRUP** can lead to drowsiness and dizziness it is recommended that no tools or machines are used while taking T**ENSOPYN PAEDIATRIC SYRUP.**

Taking other medicines with TENSOPYN PAEDIATRIC SYRUP:

If you or your child is taking **TENSOPYN PAEDIATRIC SYRUP** with other medicines which have calming effects such as medicines containing alcohol or medicines which cause sleepiness or drowsiness. **TENSOPYN PAEDIATRIC SYRUP** may enhance these symptoms. (Refer "INSTRUCTION BEFORE TAKING TENSOPYN PAEDIATRIC SYRUP")

If you or your child is taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TENSOPYN PAEDIATRIC SYRUP** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO ADMINISTER TENSOPYN PAEDIATRIC SYRUP

Always take **TENSOPYN PAEDIATRIC SYRUP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Infants: 6 months to 1 year:	2,5 ml (half a medicine measure) every four hours.
Children I - 5 years:	5,0 ml (one medicine measure) every four hours.
Children 6 – 12 years:	5 to 10 ml (one to two medicine measures) every four hours.

TENSOPYN PAEDIATRIC SYRUP should not be administered more than four times daily.

If you have the impression that the effect of **TENSOPYN PAEDIATRIC SYRUP** is too strong or too weak, talk to your doctor or pharmacist.

DO NOT EXCEED THE STATED DOSE.

If your child takes more TENSOPYN PAEDIATRIC SYRUP than he or she should:

TENSOPYN PAEDIATRIC SYRUP contains paracetamol and codeine 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.

If you or your child accidentally take more **TENSOPYN PAEDIATRIC SYRUP** than you should or someone else takes your medicine you should tell your doctor or pharmacist at once. If neither is available, contact the nearest hospital or poison control centre immediately. Show any left-over medicines or the empty bottle or carton to the doctor.

Prompt treatment is essential. If you or your child take an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that the antidote is given too late to be effective. Liver damage is possible if effective treatment is not given immediately. Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest Poison Centre. Dosages in excess of those recommended may cause severe liver damage. Overdosage is very dangerous in young children

If you forget to take TENSOPYN PAEDIATRIC SYRUP:

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

TENSOPYN PAEDIATRIC SYRUP can have side effects.

Not all side-effects reported for **TENSOPYN PAEDIATRIC SYRUP** are included in this leaflet. Should your child's general health worsen while taking **TENSOPYN PAEDIATRIC SYRUP**, please consult your doctor, pharmacist or other health care professional for advice.

Stop taking **TENSOPYN PAEDIATRIC SYRUP** and contact your doctor or pharmacist if your child begins to itch, becomes short of breath or wheezy, develops swelling of the face, hands, feet, mouth, throat and eyes. These are allergic reactions. Your child may be allergic to **TENSOPYN PAEDIATRIC SYRUP.**

Paracetamol:

Skin rashes may occur. Patients suffering from kidney or liver disease should take **TENSOPYN PAEDIATRIC SYRUP** under medical supervision.

Codeine phosphate:

Codeine may cause nausea, vomiting, dizziness, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, faintness, sleepiness and difficult breathing.

Breathing problems may be especially likely to occur in children younger than 2 years of age.

Unusual excitement or restlessness may occur in children receiving **TENSOPYN PAEDIATRIC SYRUP.**

Prolonged use of high doses of codeine has led to dependence.

6. STORING AND DISPOSING OF TENSOPYN PAEDIATRIC SYRUP:

Store at or below 25 ºC. Protect from light. Keep the container in the outer carton. Keep the container tightly closed.

Do not use after the expiry date stated on the label.

Keep all medicine out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7 PRESENTATION OF TENSOPYN PAEDIATRIC SYRUP:

Amber glass bottle of 100 ml, fitted with a white plastic cap with a tamper-evident break ring, packed into an outer carton.

8 IDENTIFICATION OF TENSOPYN PAEDIATRIC SYRUP:

A clear, colourless to pale yellow/brown syrup, with an odour and taste of fresh cherries.

9 REGISTRATION NUMBER/REFERENCE NUMBER:

W/2.8/23

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

Cipla Medpro (Pty) Ltd

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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