PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

BETAPYN Tablets

Each tablet contains:

Codeine phosphate 10 mg

Doxylamine succinate 5 mg

Paracetamol 450 mg

Caffeine anhydrous 50 mg

Sugar free

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

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

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

What is in this leaflet:

1. What BETAPYN is and what it is used for
2. What you need to know before you take BETAPYN

3. How to take BETAPYN
4. Possible side effects
5. How to store BETAPYN
6. Contents of the pack and other information

What BETAPYN is and what it is used for

BETAPYN is a pain and fever combination of paracetamol with codeine phosphate. Doxylamine succinate has sedating and antihistamine properties. In combination these all treat mild to moderate pain, tension and/or fever.

What you need to know before you take BETAPYN tablets

Do not take BETAPYN:

- if you are hypersensitive (allergic) to any of the above listed ingredients of BETAPYN.
- if you have respiratory depression (unusually struggling to breathe), especially in the presence of cyanosis (blueish discoloration of skin) and are coughing up phlegm.
- if you suffer from alcoholism, head injuries and conditions in which intracranial (inside skull) pressure is raised.
- if you or the person being treated is having an attack of bronchial asthma or in heart failure secondary to chronic lung disease.
- if your liver function is severely impaired.
- Caffeine should be given with care to patients with peptic ulceration.
- Safety of BETAPYN during pregnancy and lactation has not been established.

Warnings and precautions

Take special care:

- as this product 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.

- as this medicine may lead to drowsiness and impaired concentration, which is worsened by taking alcohol, or other antidepressant or sedative drugs that cause drowsiness, at the same time.
- With the use of atropine and tricyclic antidepressants as their effects may be enhanced.
- If you suffer from myasthenia gravis.
- if you suffer from active stomach ulcers.
- if you take more than the recommended dosage, as excess doses of Paracetamol may cause severe liver and kidney damage.
- as codeine should be given with caution to patients with low thyroid function, Addison's disease (low levels of cortisol or aldosterone hormones), liver damage, enlarged prostate or shock.
- as it should be used with caution in patients with inflammatory or obstructive bowel disorders.
- if you are elderly or you are physically weak as your dosage may need to be reduced.
- as this medicine contains Doxylamine succinate, and should be used with care in patients with glaucoma (increased pressure in the eye ball) and prostatic hypertrophy (prostate gland enlargement).
- particularly at the start of therapy, against driving vehicles, operating machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.
- to not administer to children under 12 years of age.
- so as not to take more than the maximum daily dose, with continuous use of BETAPYN, as may lead to dependency and addiction.

Children and adolescents

Do not give BETAPYN to children 12 years old and younger.

Other Medicines and BETAPYN

Always tell your healthcare professional if you are taking any other medicine, including complementary or traditional medicines.

BETAPYN should not be taken together with hypnotics, antidepressant and sedative drugs. The combined effect can cause major drowsiness and severely impaired breathing, concentration, vision, speech and alertness. Doxylamine can reduce antinausea drug effects.

BETAPYN with food and drink and alcohol

BETAPYN should not be taken together with alcohol. The combined effect can cause major drowsiness and severely impaired breathing, concentration, vision, speech and alertness.

Pregnancy, breastfeeding and fertility

Safety in fertility, pregnancy and lactation has not been established.
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 professional for advice before taking this medicine.

Driving and using machines

Patients should be warned against driving vehicles, using machinery or performing potentially hazardous tasks where loss of concentration and alertness caused by BETAPYN, may lead to accidents and injury.
It is not always possible to predict to what extent BETAPYN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BETAPYN affects them.

3. How to take BETAPYN

Do not share medicines prescribed for you with any other person.
Always take BETAPYN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Adults and children over 12 years:
Take one or two tablets repeated every four hours (up to six times a day), only if necessary.
Do not take more than eight tablets per day.
DO NOT EXCEED THE RECOMMENDED DOSE

If you take more BETAPYN than you should
Symptoms of overdosage include nausea and vomiting. Liver damage, which may be fatal, may only appear after a few days. Kidney failure has been found during severe intoxication with BETAPYN.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center immediately.

If you forget to take BETAPYN
Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects
BETAPYN can have side effects.
Not all side effects reported for BETAPYN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BETAPYN, please consult your health care provider.

Tell your doctor immediately if you notice any of the following:

Frequent:

- insomnia, deep sleep, drowsiness, sedation, lassitude (physical or mental weariness), hypotension;
- confusion, inability to concentrate;
- incoordination, dizziness, light headedness;
- headache;
- dry mouth;

- nervousness;
- tremors, convulsions;
- facial flushing.

Frequency not known:

- Skin rashes;
- Allergy/anaphylaxis,
- Sweating;
- Disorders of the blood;
- Bradycardia (slow heart rate);
- Tinnitus (permanent hearing loss);
- Miosis (excessive constriction of the pupil of the eye);
- Scintillating scotoma (Shiny blind spot in your vision);
- GIT disorders (disturbances/ulceration);
- Hypothermia (abnormal low body temperature);
- Hepatobiliary disorders;
- Psychiatric disorders;
- Muscular weakness and twitching;
- Pain in lower back area;
- Pus in the urine;
- Difficulty passing urine;
- Slow pulse or palpitations (irregular heart beat);
- Drop in blood pressure upon standing causing light-headedness, facial flushing and vertigo (dizzy spells);
- Constipation;
- Nausea and vomiting;
- Diarrhoea or;
- Dry mouth.

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.

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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 BETAPYN.

You may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. How to store BETAPYN

Store all medicines out of reach of children.

Store at or below 30 ºC in a cool, dry place.

Do not remove the blister pack from the outer carton until required for use.

Do not store in bathrooms.

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

Do not use BETAPYN if you notice any visible signs of deterioration.

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 BETAPYN contains

The active substances are:

Paracetamol 450 mg

Caffeine anhydrous 50 mg

Codeine phosphate 10 mg

Doxylamine succinate 5 mg

The other ingredients are:

Nipastat/ salistat (Total parabens), colour yellow 14037, hydrogenated cottonseed oil, magnesium stearate, microcrystalline cellulose, pregelatinized starch, starch maize, sodium starch glycollate.

What BETAPYN looks like and contents of the pack

BETAPYN tablets are round, yellow, flat tablets, bisected on one side of 12,7 mm and embossed with “BETAPYN” on reverse side.

They come in blister packs of 18, 20 and 40 tablets.

All pack sizes may not be marketed simultaneously.

Holder of Certificate of Registration

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