PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

PAINAMOL® PLUS 500 mg/8 mg tablets

Paracetamol/Codeine phosphate

Contains sugar: Sucrose 20,0 mg per tablet

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PAINAMOL® PLUS 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.

What is in this leaflet

1. What Painamol® Plus is and what it is used for

The name of your medicine is PAINAMOL® PLUS. It contains paracetamol and codeine which are indicated for the relief of mild to moderate pain and for the reduction of temperature in febrile conditions

2.What you need to know before you take PAINAMOL® PLUS TABLETS

Do not take PAINAMOL® PLUS :

- if you are hypersensitive (allergic) to paracetamol or codeine or any other ingredients of PAINAMOL® PLUS (listed in section 6)
- If you have asthma or another lung disease which makes breathing difficult
- If you are an alcoholic.
- If you have increase pressure in the brain, e.g following a head injury
- If you have heart failure secondary to lung disease
- If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment

Warnings and precautions

Take special care with PAINAMOL® PLUS :

- if you going to use continuously for more than (five) 5 days without consulting your doctor
- if you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- if exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction
- if you have hypothyroidism (overactive thyroid), adrenocortical insufficiency (body does not produce enough of certain hormones) or myasthenia gravis(neuromuscular disease that causes weakness in skeletal muscles)
- if you have an impaired renal function, impaired liver function,
- if you have an enlargement of the prostate

- if you have inflammation or obstructive bowel disorders.
- If you are elderly and a debilitated patients.
- if you are an alcoholic , taking anaesthetics, hypnotics and sedatives, phenothiazines, tricyclic antidepressants.
- if you are in labour as codeine may cause respiratory depression in the new born infant
- if you are allergic to tartrazine which may cause an allergic reaction
- 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 DrugReaction 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.
- If the patients have a personal or family history of substance abuse or mental health disorders, then there is an increased risk of addiction

Other medicines and PAINAMOL® PLUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- medicines used to treat water retention or high blood pressure
- medicines to treat mental illness (anti-psychotics)
- medicines to prevent blood clotting, such *as* warfarin
- medicines to treat diarrhoea, such *as* loperamide and kaolin
- muscle relaxants, such as atropine
- anaesthetics or other drug~ used in surgery (such as neuromuscular blocking agents)
- medicines that affect the liver e.g. carbamazepine, phenobarbital,phenytoin (anti-epileptics) or rifampicin (antibiotic)
- naloxone or naltrexone (used to treat drug abuse or overdose)
- colestyramine (used to reduce cholesterol in the blood)
- quinidine or mexiletine (used to treat certain heart conditions)
- metoclopramide or domperidone (used to treat nausea and vomiting)
- cimetidine (used to treat stomach ulcers)
- cisapride (used to treat heart burn)
- hydroxyzine (an anti-histamine)
- probenecid (used to treat gout)
- isoniazid (used to treat tuberculosis).

Pregnancy, breast-feeding and fertility

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 health care provider for advice before taking
this medicine.

Driving and using machines

PAINAMOL® PLUS contains codeine. Codeine may cause drowsiness, if affected patients

should be advised not to drive or operate machinery.

PAINAMOL® PLUS contains sucrose:

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

3. How to take PAINAMOL® PLUS

Do not share medicines prescribed for you with any other person. Always take PAINAMOL® PLUS exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: One or two tablets every four to six hours. Children over 12 years: One tablet every four to six hours. Children 6 to 12 years: Half to one tablet every six hours. Do not exceed an adult dose of 8 tablets per day. Do not use continuously for longer than five (5) days without consulting your doctor.

If you have the impression that the effect of PAINAMOL® PLUS is too strong or too weak, tell your doctor or pharmacist

If you take more PAINAMOL® PLUS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PAINAMOL® PLUS

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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

4. Possible side effects

PAINAMOL® PLUS can have side effects.

Not all side effects reported for PAINAMOL® PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PAINAMOL® PLUS, please consult your health care provider for advice.

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

- An allergic reaction may include: Any kind of skin rash, flaking skin, boils or sore lips and mouth
- In rare cases, severe allergic reaction (anaphylactic shock) may occur which may include sudden itching of the skin, wheezing, fluttering or tightness of the chest, or collapse.

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

Tell your doctor if you notice any of the following:

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

Less frequent side effects:

- Steven Johnson Syndrome(serious disorder of the skin and mucuous membrane)
- Exanthemathous pustolosis(acute eruptions of pustules)
- Fixed drug erruptions
- Allergic reactions including skin rash

- 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 r ash, 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.
- 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

- Agranulocytosis (low number of a type of white blood cells)
- Thrombocytopenia (low blood platelet count)
- Allergic reactions including rash, itching, difficulty in breathing including shock.
- Drug dependence
- Dizziness, light-headedness, confusion, drowsiness

- Inflammation of the pancreas, constipation, nausea, vomiting
- Urinary retention (unable to emptying all the urine from the bladder)
- Drug withdrawal syndrome
- Changes in mood
- Reslessness
- Pressure inside the skull
- Constriction of pupils of the eye
- Middle ear imbalance
- Slow heart rate,
- fast hear beat
- Low blood pressure
- Dry mouth
- Spasm in the urethra
- Muscle rigity
- Diificulty in urination, sweating

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 "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/

Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

By reporting side effects, you can help provide more information on the safety of Painamol® Plus.

5. How to store PAINAMOL® PLUS.

Store in a cool, dry place, at or below 25 ^{0}C and protect from light. Store all medicines out of reach of children.

Store in the original package.

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)

6.Contents of the pack and other information

What PAINAMOL® PLUS contains

The active ingredient is paracetamol 500 mg and codeine phosphate 8 mg

The other ingredients are: alcohol 90 % v/v, be-tabs red C344/TF, gelatin, magnesium stearate, modified starch, povidone, powdered sucrose, purified water, sodium metabisulphite, starch maize, yellow saffron LS2002/22

What PAINAMOL® PLUS looks like and contents of the pack

Flat yellow and red mottled tablet, scored on the one side and a "b" embossed on the other side

Contents of the pack:

Cartons with 2 X 10 tablets in push through blister packs. (not currently marketed

Containers with 500 and 1000 tablets (not currently marketed)

Containers with 100

Blue/green plastic buckets containing 5000 tablets. (not currently marketed)

Patient ready packs of different pack sizes. (not currently marketed)

Not all pack sizes are marketed

Holder of Certificate of Registration Ranbaxy Pharmaceuticals

(Pty) Ltd 14 Lautre Road

Stormill Ext.1 Roodepoort, 1724

South Africa

Telephone: +27(0) 12 643 2000

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