Watsons Pain & Fever Relief EXTRA Tablet

(Paracetamol 500mg, Caffeine 65mg)

What is in this leaflet

1. What Watsons Pain & Fever Relief EXTRA Tablet is used for
2. How Watsons Pain & Fever Relief EXTRA Tablet works
3. Before you use Watsons Pain & Fever Relief EXTRA Tablet
4. How to use Watsons Pain & Fever Relief EXTRA Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Watsons Pain & Fever Relief EXTRA Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

1. What Watsons Pain & Fever Relief EXTRA Tablet is used for

Watsons Pain & Fever Relief EXTRA Tablet is used for the treatment of most painful and febrile conditions, for example:

- Headache, including migraine
- Toothache
- Rheumatic pain
- Menstrual pain
- Relief of the symptoms of colds, influenza and sore throat

2. How Watsons Pain & Fever Relief EXTRA Tablet works

The tablet contains 500mg Paracetamol, 65mg Caffeine. Paracetamol works by relieving pain.

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) (specifically cyclooxygenase (COX)-2) and, to a lesser extent, through a peripheral action by blocking pain-impulse generation.

Caffeine is a CNS stimulant. It stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

Contact your doctor if you have any questions about the purpose of the Watsons Pain & Fever Relief EXTRA Tablet provided to you. Your doctor may prescribe Watsons Pain & Fever Relief EXTRA Tablet for other purposes.

3. Before you use Watsons Pain & Fever Relief EXTRA Tablet

- *When you must not to use it*

  Do not consume this medicine if you have allergies towards:
  - Paracetamol and any other ingredients listed at the end of this leaflet
  - Any other medicine which are similar

  Do not consume Watsons Pain & Fever Relief EXTRA Tablet if you are:
  - taking other medicine that contains paracetamol

  If you experience any of the above conditions, consult your doctor or pharmacist.

  Do not consume Watsons Pain & Fever Relief EXTRA Tablet after the expiration date on this packaging or if there is a misuse of the packaging.

  If the packaging is expired or damaged, return it to your pharmacy for disposal. If you are not sure whether you should start taking this medicine, please consult your doctor.

  Usage during pregnancy and breastfeeding:

  Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption. Caffeine in breast milk may potentially have a stimulating effect on breast fed infants. Due to the caffeine content of this product it should not be used if you are pregnant or breast feeding.

- *Before you start to use it*

  Please consult your doctor if you have any of the following:
  - Allergy to any medicine, food, preservatives or coloring.
  - Impairment of kidney or liver function.
  - Addiction to alcohol.

  If you are pregnant or breastfeeding, consult your doctor or pharmacist before consuming this medicine.

  If you have high blood pressure, glaucoma, or overactive bladder syndrome.

  If you haven't informed your doctor about any of the above, consult them before you start consuming Watsons Pain & Fever Relief EXTRA Tablet.

  Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcohol liver disease.

- *Taking other medicines*

  Tell your doctor or

Watsons Pain & Fever Relief EXTRA Tablet

(Paracetamol 500mg, Caffeine 65mg)

Pharmacist if you are consuming other medication, such as warfarin and coumarins. Your doctor or pharmacist will have more information regarding medicines that are to be taken note of during the consumption of Watsons Pain & Fever Relief EXTRA Tablet or anything that should be avoided.

The speed of absorption of paracetamol may be increased by metaclopramide or domperidone and reduced by colestyramine.
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4. Before you use Watsons Pain & Fever Relief EXTRA Tablet

Follow all instructions given by your doctor or pharmacist carefully. These instructions may differ from the information contained in this brochure.

If you do not understand the instructions on this package, consult your doctor or pharmacist.

- *How much to use*
  For oral adminstration only. Adults and children (12 years and older): 1-2 tablets four times daily as required. The dose should not be repeated more frequently than every 4 hours. Do not exceed 8 tablets in 24 hours.

  Not recommended for children under 12 years.

- *When to use it*
  Take your medicine as directed by your doctor.

- *How long to use it*
  Continue taking Watsons Pain & Fever Relief EXTRA Tablet as directed by your doctor. Please seek immediate medical advice if sickness lasts longer than 10 days, or if there is redness or fever lasting for more than 3 days.

- *If you forget to use it*
  Take the remaining dose as soon as you remember and then return to your usual recommended dosage. If the next dosage period is near, leave the forgotten dosage and take the next dosage on schedule as usual. Do not take double the dosage to replace the forgotten dosage by taking more than one dosage at the same time. This may increase your chances of experiencing side effects. If you are not sure what to do, consult your doctor or pharmacist. If you have problems remembering when to take your medication, please seek advice from your pharmacist.

- *If you use too much(overdose)*
  The toxic symptoms of paracetamol overdose include vomiting, stomach aches, low blood pressure and sweating. More serious side effects include necrosis liver failure. Clinical and laboratory evidence for risk of liver failure may take up to 1 week to be detected. The main manifestations of liver failure are jaundice, hypoglycemia and metabolic acidosis which may take at least 3 days to develop.

  If you or someone else may have taken an overdose of Watsons Pain & Fever Relief EXTRA Tablet, contact your doctor for advice or go to the nearest hospital emergency room immediately. This must be done without any sign of discomfort or poisoning. You may need medical attention immediately.

5. While you are using it

- *Things you must do*
  Always follow your doctor's instructions carefully. If you are about to start on any new medication, consult your doctor and pharmacist that you are taking Watsons Pain & Fever Relief EXTRA Tablet.

  Consult with a doctor if your headaches become persistent.

  Avoid other caffeine containing products. Too much caffeine may cause rapid heart rate, nervousness or sleeplessness.

  Excessive intake of caffeine (e.g.: coffee, tea and some canned drinks) should be avoided while taking this product.

- *Things you must not do*
  Do not take more than the recommended dose unless advised by your doctor. Use the smallest effective dose. Taking more than the maximum daily dose may cause severe or possibly fatal liver damage.

  Do not take Watsons Pain & Fever Relief EXTRA Tablet to treat any other illness unless instructed by your doctor. Do not prescribe the same dosage to others, even if they are experiencing similar symptoms.

6. Side effects

Adverse reactions of

Watsons Pain & Fever Relief EXTRA Tablet

(Paracetamol 500mg, Caffeine 65mg)

paracetamol-caffeine are rare when taken in recommended doses, but some undesirable effects such as skin rash or itching have been reported, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
Bruising or bleeding.

Adverse Effect of Paracetamol
The side effects are rare and have been reported according to the body system;
Thrombocytopenia and agranulocytosis (blood and lymphatic system disorders), anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson Syndrome/toxic epidermal necrolysis (immune system disorders), bronchospasm (respiratory, thoracic and mediastinal disorders), hepatic dysfunction (hepatic effects).

Adverse Effect of Caffeine
Nervousness and dizziness have been reported for the CNS.

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations

Tell your doctor if you observe anything that makes you feel unwell. Other side effects not listed above may occur in some patients.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of Watsons Pain & Fever Relief EXTRA Tablet

- *Storage*
  Keep your medicine in its package. If you take the medicine out of the package, it may not be maintained in a good condition.

  Store your medicine in a dry place at temperatures below 30°C. Keep it away from sunlight.

  Keep the medicine in a place that is out of reach from children.

- *Disposal*
  If your doctor tells you to stop consuming Watsons Pain & Fever Relief EXTRA Tablet or this medicine has passed its expiration date, please consult your pharmacist on what is required for any remaining medications.

  Medicines should not be disposed of through wastewater or household waste. Please consult your pharmacist about the correct way to dispose of any medications that you no longer need. These measures can help protect the environment.

8. Product Description

- *What it looks like*
  A white, modified capsule shaped, 0.662 x 0.300" in diameter, convex, bisected line on one side and plain in the other side

- *Ingredients*
  Active ingredients:
  - Paracetamol 500mg
  - Caffeine 65mg

  Inactive ingredients:
  - Corn Starch
  - Magnesium Stearate
  - Povidone K-30
  - Sodium Starch Glycolate

- *MAL number*
  MAL xxxxxxxxxx

9. Manufacturer and Product Registration Holder

Manufacturer:
PT. Medifarma Laboratories
Jl. Raya Jakarta - Bogor Km.33,
Kelurahan Curug, Kecamatan Cimanggis, Kota Depok, Jawa Barat, Indonesia

Product Registration Holder:
Unam Pharmaceutical (M) Sdn. Bhd
Suite 803, Block F, Phileo Damansara 1,
No. 9, Jalan 16/11, 46350 Petaling Jaya,
Selangor Malaysia

10. Date of revision
29/11/2021

11. Serial Number
NPRA (R2) 21/026