

# Panadol Joint Tablets

(Analgesic/Antipyretic)

## PRODUCT INFORMATION



### Description

Panadol Joint is formulated as a bilayer tablet which provides a pain relief which may last up to 8 hours.

### Each tablet contains:

Paracetamol Ph. Eur. 665 mg

### Other Ingredients:

Hypromellose, starch-pregelatinised, povidone, magnesium stearate, croscarmellose sodium, stearic acid, triacetin, carnauba wax.

### What is Panadol Joint and what is it used for?

Panadol Joint is a bilayer tablet having incorporating an immediate release and a sustained release dose of Paracetamol which provides a pain relief which may last up to 8 hours.

Panadol Joint is analgesic and antipyretic.

- Panadol Joint relieves mild to moderate pain of Osteoarthritis and Muscle aches.
- It also relieves mild to moderate pain including: headache, sore throat, pain after dental procedures/ tooth extraction, toothache, dysmenorrhoea, Musculoskeletal pain, cold & flu and relieves fever and pain after vaccination.

### How to take Panadol Joint?

For oral administration only.

Do not exceed the stated dose.

- The lowest dose necessary to achieve efficacy should be used with the shortest duration of treatment.
- can be taken with or without food
- Swallow whole tablet. Do not chew or suck, as it impairs the sustained release properties.
- Minimum dosing interval: 6 hours
- Maximum Daily dose: 4000 mg
- Should not be used for more than 48 hours for children aged 12-17 years except on medical advice
- The tablets should not be crushed

### Adults (including the elderly) and children aged 12 years and over:

- 2 tablets (1330 mg) taken three times a day, every 6 to 8 hours as required
- Do not take more than 6 tablets (4000mg paracetamol) in 24 hours.
- Do not take more frequently than every 6 hours.

### Children:

Panadol Joint is not recommended for children under 12 years of age.

### Before you take Panadol Joint

#### a. Do not take Panadol Joint in case of:

Known or previous history of hypersensitivity to paracetamol, or any other ingredient in the product.

#### b. Take special care with Panadol Joint if:

- You have been diagnosed with liver or kidney impairment (Because Paracetamol is metabolised in the liver and excreted by the kidney in urine). Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.
- Underlying liver disease increases the risk of Paracetamol related liver damage
- Your symptoms do not improve, get worse or new symptoms persist, you must consult your doctor as these could be signs of serious condition.

Check with your doctor if:

- You have glutathione depleted states such as sepsis, severely malnourished, anorexic, have low body mass index or chronic heavy users of alcohol or you have a severe infection as the use of Paracetamol may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- Deep, rapid, difficult breathing
- Feeling sick (nausea), being sick (vomiting)
- Loss of appetite

- Contact a doctor immediately if you get a combination of these symptoms.
- Keep this and all medication out of sight and reach of children.
- Do not exceed the stated dose.

- This product contains Paracetamol, do not take with any other product containing Paracetamol. The concomitant use with other products containing paracetamol may lead to an overdose.

#### c. Taking other medicines:

- The liver toxic effects of Paracetamol may be increased by the use of alcohol.
- 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.
- Paracetamol absorption is increased by substances that increase gastric emptying, eg metoclopramide.
- Paracetamol absorption is decreased by substances that decrease gastric emptying, eg propantheline, antidepressants with anticholinergic properties and narcotic analgesics.
- Paracetamol may increase chloramphenicol concentrations.
- The risk of Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant drugs.
- Paracetamol excretion may be affected and plasma concentrations altered when given with probenecid
- Colestyramine reduces the absorption of Paracetamol if given within one hour of Paracetamol.

### d. Pregnancy & breast feeding:

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and

shortest duration of treatment should be considered. Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breastfeeding.

### e. Driving and using machines:

Panadol Joint is unlikely to cause an effect on ability to drive and use machines.

### Possible Adverse events

These reactions are very rare.

Stop using Panadol Joint and consult your doctor immediately if:

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience Anaphylaxis, cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, Stevens-Johnson syndrome and Toxic Epidermal Necrolysis
- You experience a skin rash or peeling or mouth ulcers.
- You have previously experienced breathing problems or bronchospasm with acetylsalicylic acid or non-steroidal anti-inflammatory, and experience a similar reaction with this product.
- You experience unexplained bruising or bleeding.
- You experienced liver dysfunction related symptoms or signs.

### Overdose

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity. Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

Experience following overdose with paracetamol indicates that the clinical signs of liver injury usually occur after 24 to 48 hours and have peaked after 4 to 6 days. Because paracetamol 665mg modified release tablets are a sustained-release product, absorption will be prolonged in overdose, the maximum plasma concentration may occur later, and high concentrations, in particular after large doses, may persist for several days.

The usual protocols of sampling and treatment regimens used in the management of overdose with immediate release paracetamol formulations are therefore not adequate

- Where overdose with  $\geq 10g$  of paracetamol (or  $\geq 150$  mg/kg body weight in children) is known or suspected, or where dose is unknown, treatment with NAC should be started immediately regardless of the initial serum paracetamol level
- Where  $<10$  g of paracetamol have been ingested and time since ingestion is known, multiple serum paracetamol samples should be taken at suitable intervals (e.g. 4, 6, and 8 hours after ingestion). Additional samples should be considered if serum paracetamol concentrations are not declining to low level. If serum paracetamol levels exceed the treatment nomogram at any time point, treatment with antidote (NAC) is indicated
- If time since ingestion is unknown or serum paracetamol concentration cannot be obtained within 8 hours of the overdose, it is recommended that treatment with antidote (NAC) should be initiated without waiting for serum paracetamol concentrations to be available
- If NAC treatment has been initiated, it should be prolonged beyond the first 21-hour NAC course if paracetamol level remains above the limit of detection (or greater than 10 mg/L) or if ALT is increasing (greater than 100 U/L), and should be continued until paracetamol is below the limit of detection (or 10 mg/L) or if ALT is falling below 100 U/L.

prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

### How to store Panadol Joint?

Store below 30°C.

This product is protected in a sealed blister. Do not use if blister is broken.

### THIS IS A MEDICINE

- **Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctors' prescription, the method of use and the instructions of the pharmacist who sold the medicine.**
- **The doctor and pharmacist are experts in the use of medicines, its benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribe for you.**
- **Do not repeat the same prescription without consulting your doctor.**

**KEEP MEDICINE OUT OF REACH OF CHILDREN**

**Council of Arab Health Ministers  
Union of Arab Pharmacists**

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### Final Batch Releaser:

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