

PATIENT INFORMATION LEAFLET

Gigapyn[®] Caplets

Paracetamol 500mg and Codeine Phosphate 8mg caplets

Read all of this leaflet carefully before taking this medication

- Keep this leaflet as you may need to read it again
- If you still have questions after reading this leaflet, ask your doctor, health care provider or pharmacist.
- This medicine has been indicated for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet you will find information on:

- a. What are Gigapyn[®] Caplets and what are they used for?
- b. Before you take Gigapyn[®] Caplets
- c. How to take Gigapyn[®] Caplets
- d. Possible side effects
- e. How to store Gigapyn[®] Caplets
- f. Further information

a. What is Gigapyn[®] Caplets and what is it used for?

Gigapyn[®] Caplets contain the active ingredients Paracetamol and Codeine. Gigapyn[®] Caplets are used for short-term treatment of acute moderate pain not relieved by other analgesics, such as headache, period pains, neuralgia, toothache, and rheumatic pains.

b. Before you take Gigapyn[®] Caplets

Do not take Gigapyn[®] Caplets

If you are hypersensitive (allergic) to Paracetamol or codeine phosphate or any of the ingredients. (See **What Gigapyn[®] Caplets contains**).

Taking other medicines

Metoclopramide or Domperidone can speed up paracetamol absorption, while cholestyramine can slow it down. Regular use of paracetamol may enhance the anticoagulation effect of warfarin and other coumarins, increasing bleeding risk. Codeine can delay Mexiletine absorption, reducing its antiarrhythmic effect. The depressant effects of codeine are heightened by central nervous system depressants like hypnotics and sedatives. Additionally, codeine may counteract the gastrointestinal effects of metoclopramide and Domperidone.

Taking Gigapyn[®] Caplets with food and drink

Take Gigapyn[®] Caplets after food.

Pregnancy and breast-feeding

Gigapyn caplets are not recommended during pregnancy due to safety concerns, especially with codeine's potential risks. Codeine should also be avoided while breastfeeding, as it can pass into breast milk at low levels but may cause harm in infants. Paracetamol is considered safe for use during pregnancy and breastfeeding when used at the lowest effective dose for the shortest time possible.

Driving and using machines

This medicine may impair cognitive function and affect the ability to drive safely. Patients should be informed that it can impact their driving ability, they should not drive until they understand its effects, and driving under its influence is an offense unless prescribed for a medical issue, taken as directed, and does not hinder safe driving.

c. How to take Gigapyn[®] Caplets

Adults: One to two caplets, taken with water every four to six hours if required, up to a maximum of 8 caplets in 24 hours.

Children aged 16 to 18 years: One or two caplets every 6 hours when necessary up to a maximum of 8 caplets in 24 hours.

Children aged 12 to 15 years: One caplet every 6 hours when necessary up to a maximum of 4 caplets in 24 hours.

Children aged less than 12 years: Codeine should not be used in children below the age of 12 years because of the risk of opioid toxicity.

Do not take for more than 3 days continuously without consulting a doctor.

If you take more Gigapyn[®] Caplets than you should

Paracetamol overdose can lead to liver damage, especially if 10g or more is taken by adults. Risk factors include long-term use of certain medications, excessive alcohol consumption, and conditions that deplete glutathione levels. Symptoms within the first 24 hours may include pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage can manifest within 12 to 48 hours after ingestion. Immediate medical attention is crucial for managing paracetamol overdose even if symptoms are mild initially. Treatment guidelines should be followed promptly, including considering activated charcoal if taken within an hour and measuring plasma paracetamol concentration at least 4 hours post-ingestion.

d. Possible side effects

The most common side effects are nausea, vomiting, constipation, dry mouth, sweating, skin rashes and other allergic reactions. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Paracetamol: very rare cases of serious skin reactions have been reported.

Regular prolonged use of codeine is known to lead to addiction and symptoms of restlessness and irritability may result when treatment is then stopped.

Prolonged use of a painkiller for headaches can make them worse.

e. How to store Gigapyn[®] Caplets

Keep out of the reach of children.

Do not store above or not store above 30° C, in a dry environment away from light.

Do not use Gigapyn[®] Caplets after the expiry date which is stated on the label. Do not use Gigapyn[®] Caplets if you notice any visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

f. Further information

What Gigapyn[®] Caplets contains

- The active ingredients are Paracetamol 500mg and Codeine Phosphate 8mg per caplet.

- The other ingredients are- Pregelatinized maize starch, maize starch, povidone (PVP – K30), potassium sorbate, purified talc, stearic acid, purified water.

What Gigapyn[®] Caplets look like and contents of the pack

White to off-white capsule shaped tablet with a half score on both sides and embossed 'P' and 'C' on one side.

Category for Distribution:

Zimbabwe: P

Namibia: NS1

Rwanda: POM

Registration Number:

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**NAME AND FULL PHYSICAL ADDRESS OF MARKETING
AUTHORIZATION HOLDER AND
MANUFACTURING SITE:**

Varichem Pharmaceuticals (Pvt) Ltd
194 Gleneagles Road
Willowvale
Harare
Zimbabwe
Tel: +263 (04) 620181-7

For any information about this medicinal product, please contact **Activis
Pharma** supplier:

Company Name: **Activis Pharma**
Address: **P. O. Box 2927 Kigali**
**KN 2 Ave, Rwezamenyo II - Nyarugenge (Opposite St
Andre college)**
Country: **Rwanda**
Telephone: **+250 732 888 826**
E-Mail: activispharma@gmail.com

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