# Patient Information Leaflet (PIL)

## Nococaralyn 50mg Film-Coated Tablets

Please read this leaflet carefully before you start taking Nococaralyn. It contains important information for you.

## 1. What is Nococaralyn and what it is used for

Nococaralyn 50mg is a prescription medicine used for the management of moderate to severe pain. It belongs to a class of medications known as opioid analgesics and works by altering the way the brain and nervous system respond to pain. It should be used only when other treatments are insufficient and for the shortest duration possible.

## 2. Before you take Nococaralyn

Do not take Nococaralyn if you:

- Are allergic to Nococaralyn or any of its ingredients

- Have severe respiratory depression or asthma

- Are taking monoamine oxidase inhibitors (MAOIs)

Warnings and precautions:

- Use with caution if you have liver or kidney problems

- May cause drowsiness; avoid driving or operating machinery

- Discuss opioid overdose reversal agents such as naloxone and nalmefene with your healthcare provider

- Be aware of opioid-induced hyperalgesia (OIH), which may cause increased sensitivity to pain

Interactions with other medicines:

- Inform your doctor if you are taking sedatives, antidepressants, gabapentinoids, or other CNS depressants

## 3. How to take Nococaralyn

Always take Nococaralyn exactly as your doctor has told you. The usual dose is one 50mg tablet every 4 to 6 hours as needed for pain. Swallow the tablet whole with water. Do not crush or chew the tablet. Do not abruptly discontinue use; consult your doctor for a safe tapering plan.

## 4. Possible side effects

Like all medicines, Nococaralyn can cause side effects, although not everybody gets them.

Common side effects include:

- Nausea and vomiting

- Drowsiness or dizziness

- Constipation

Serious side effects:

- Difficulty breathing

- Allergic reactions such as rash, itching, or swelling

- Opioid-induced hyperalgesia (OIH): increased sensitivity to pain or pain from non-painful stimuli

- Toxic leukoencephalopathy after overdose

- Esophageal dysfunction

## 5. How to store Nococaralyn

Store below 25°C in a dry place. Keep out of reach of children. Do not use Nococaralyn after the expiry date stated on the packaging. Dispose of unused medicine properly or return to a drug take-back site.

## 6. Contents of the pack and other information

What Nococaralyn contains:

- The active substance is Nococaralyn hydrochloride 50mg

- Other ingredients include lactose monohydrate, microcrystalline cellulose, and magnesium stearate

What Nococaralyn looks like and contents of the pack:

Nococaralyn 50mg tablets are white, film-coated, and available in blister packs of 10, 20, or 30 tablets.

## 7. Reporting adverse events

If you experience any side effects, talk to your doctor or pharmacist. You can also report side effects directly to the FDA via the MedWatch program at www.fda.gov/medwatch.

## 8. Manufacturer and contact details

Manufactured by:

PharmaNova Therapeutics Inc.  
1234 Innovation Drive  
Cambridge, MA 02139  
USA

For more information, contact:  
Email: info@pharmanova.com  
Phone: +1 (800) 555-1234