

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### NAKLOFEN

50 mg Suppositories

DICLOFENAC SODIUM

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What NAKLOFEN SUPPOSITORIES is and what it is used for
2. Before you take NAKLOFEN SUPPOSITORIES
3. How to take NAKLOFEN SUPPOSITORIES
4. Possible side effects
5. How to store NAKLOFEN SUPPOSITORIES

#### 1. WHAT NAKLOFEN SUPPOSITORIES IS AND WHAT IS IT USED FOR

Diclofenac sodium, the active ingredient in NAKLOFEN SUPPOSITORIES, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

- NAKLOFEN SUPPOSITORIES relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:
  - Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis
  - Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
  - Tendonitis, tenosynovitis, bursitis.
- They are also used to treat pain and inflammation associated with dental and minor surgery.
- In children aged 1 to 12 NAKLOFEN SUPPOSITORIES 12.5 and 25 mg are used to treat juvenile chronic arthritis.
- In children aged over 6 they can also be used alone, or in combination with other painkillers, for the short term treatment of any pain experienced after an operation.

#### 2. BEFORE YOU TAKE NAKLOFEN SUPPOSITORIES

***Do not use NAKLOFEN SUPPOSITORIES if:***

- you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of NAKLOFEN SUPPOSITORIES. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type reaction
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have severe heart, kidney or liver failure
- if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- you are more than six months pregnant
- you suffer from ineffectual straining to empty the bowels, diarrhoea or rectal bleeding

***You should also ask yourself these questions before using NAKLOFEN SUPPOSITORIES:***

- Do you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease?
- Do you have kidney or liver problems, or are you elderly?
- Do you have a condition called porphyria?
- Do you suffer from any blood or bleeding disorder? If you do, your doctor may ask you to go for regular check-ups while you are using these suppositories.
- Have you ever had asthma?
- Are you breast-feeding?
- Do you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- Do you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker)?
- Do you have diabetes
- Do you smoke
- Do you have Lupus (SLE) or any similar condition?

**If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because NAKLOFEN SUPPOSITORIES might not be the right medicine for you.**

***Taking other medicines?***

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems

- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example beta- blockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

### **Pregnancy**

- Are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not use NAKLOFEN SUPPOSITORIES during the last 3 months of pregnancy as it may affect the baby's circulation.
- Are you trying for a baby? Using NAKLOFEN SUPPOSITORIES may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

### **Will there be any problems with driving or using machinery?**

Very occasionally people have reported that NAKLOFEN SUPPOSITORIES have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

### **Other special warnings**

- You should take the lowest dose of Naklofen for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Naklofen. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Naklofen may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Naklofen.

**NAKLOFEN SUPPOSITORIES 50 mg are not suitable for children.**

### **3. HOW TO TAKE NAKLOFEN SUPPOSITORIES**

The doctor will tell you how to use NAKLOFEN SUPPOSITORIES. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep using the suppositories for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Suppositories are designed for insertion into the back passage (rectum). **Never take them by mouth.**

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if

you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

### Adults

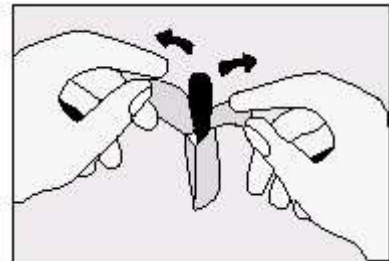
NAKLOFEN SUPPOSITORIES are normally inserted one, two or three times a day up to a maximum **total** daily dose of 150mg. The number of suppositories you need will depend on the strength which the doctor has given you.

### Elderly

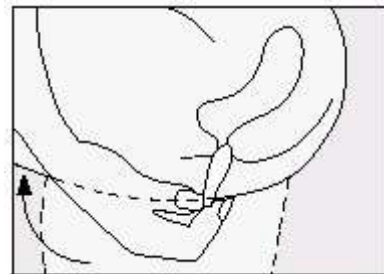
Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the NAKLOFEN SUPPOSITORIES are not affecting your stomach, particularly during the first 4 weeks that you are using the suppositories.

### How to insert the suppositories

- Empty your bowels before inserting a suppository.
- Wash your hands.
- Take out the strip of suppositories and tear off one along the perforation.
- Then take the suppository out of the plastic wrapping by pulling back the loose end.



- Lie on one side with your knees pulled up towards your chest.
- Gently push the suppository pointed end first into your back passage (rectum) with your finger. Push the suppository in as far as possible as shown in the diagram.



- Lower your legs and, if possible, stay still for a few minutes.
- If you feel as if you need to push the suppository out, try to resist this by lying still with your buttocks pressed together. It is important to keep the suppository in the rectum to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the rectum with your finger will help to reduce this feeling.
- Wash your hands.

### ***What if you forget to take a dose?***

If you forget to use a suppository, do not worry. Use one as soon as you remember. If it is nearly time for your next dose though, just take the next dose and forget about the one you missed. Do not double up the next dose to make up for the one you missed. Do not insert 2 suppositories at the same time. The total dose should not be more than 150 mg each day if you are an adult.

### ***What if you use too many suppositories?***

You should not take more than 150 mg in one day if you are an adult. If you accidentally use too many suppositories or use them too often, tell your doctor or go to your nearest casualty department straight away.

#### 4. POSSIBLE SIDE EFFECTS

NAKLOFEN SUPPOSITORIES are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

##### **Some side effects can be serious**

**Stop using the suppositories and tell your doctor straight away if you notice:**

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

NAKLOFEN SUPPOSITORIES may also occasionally cause itching or burning in your back passage or make any haemorrhoids (piles) worse.

##### **The side effects listed below have also been reported.**

##### **Common side effects (*These may affect between 1 and 10 in every 100 patients*):**

- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite ☒  
Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood
- Irritation where the suppository is inserted

##### **Rare side effects (*These may affect between 1 in every 1000 to 1 in every 10,000 patients*):**

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice

##### **Very rare side effects (*These may affect less than 1 in every 10,000 patients*):**

##### **Effects on the nervous system:**

Tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety,

mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, including congestive heart failure or heart attack, blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Effects on skin or hair:

Serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.

Hair loss.

**Other side effects that have also been reported include:**

Inflammation of the pancreas, impotence. Facial swelling, inflammation of the lining of the brain (meningitis), stroke, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye.

**Do not be alarmed by this list - most people use NAKLOFEN SUPPOSITORIES without any problems.**

**If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.**

### *5. HOW TO STORE NAKLOFEN SUPPOSITORIES*

Store in a dry place, below 30°C. Keep the suppositories in their original pack.

Keep out of the reach and sight of children.

Do not use the suppositories after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop using them, please take any unused suppositories back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.