

5. PATIENT INFORMATION LEAFLET (PIL)



DICLONOVA- SUPPOSITORIES

50mg and 100mg Suppositories diclofenac sodium

What is in this leaflet

This leaflet answers some common questions about Diclonova Suppositories.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking it against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. **Keep this leaflet with the medicine.**

You may need to read it again.

What diclonova is used for

Diclonova relieves pain and reduces inflammation (swelling and redness) that may occur in the following:

- Different types of arthritis including rheumatoid arthritis and osteoarthritis
- Other painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (eg. tennis elbow)
- Menstrual cramps (period pain)
- Migraine attacks Diclonova belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines can relieve the symptoms of pain and inflammation but they will not cure your condition. Your doctor may prescribe Diclonova for another purpose. Ask your doctor if you have any questions about why it has been prescribed for you.
- Diclonova is only available with a doctor's prescription. It is not addictive.

Before you take Diclonova

When you must not take it

Do not take Voltaren if you have an allergy to

- diclofenac (the active ingredient in Diclonova) or any of the other ingredients listed at the end of this leaflet
- Aspirin/ acetylsalicylic acid



- Any other NSAID medicine many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist. Symptoms of an allergic reaction to these medicines may include:
- Asthma, wheezing or shortness of breath
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing □ hives, itching or skin rash
- Fainting

If you are allergic to aspirin or NSAID medicines and take Diclofenac, these symptoms may be severe. Do not take Diclonova if at the present time you have an ulcer (gastric or duodenal) or bleeding from the stomach or bowel.

If you take it, your stomach problem may become worse.

Do not use Diclonova suppositories if you suffer from inflammation of the rectum (back passage).

Do not take Diclonova after the expiry date (EXP) printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not take Diclonova if the packaging is torn or shows signs of tampering.

Do not give Diclonova to children less than 5 years.

If you are not sure whether you should start taking Diclonova, contact your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Tell your doctor if, in the past, you have ever had:

- Ulcers (gastric or duodenal)
- Severe attacks of indigestion or other stomach trouble
- Diseases of the bowel (eg. Crohn's disease, ulcerative colitis)
- Bleeding from your rectum (back passage)

Tell your doctor if you have any of these health problems/medical conditions at the present time:

- Established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease), as treatment with Diclonova is generally not recommended.



- Established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke and your doctor decides to prescribe Diclonova, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- It is generally important to take the lowest dose of Diclonova
- That relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.
- Kidney disease
- Liver disease
- A tendency to bleed or other blood problems such as anaemia
- Asthma
- Haemorrhoids (piles) or irritation of the rectum (back passage)
- If you recently had or you are going to have a surgery of the stomach or intestinal tract. Your doctor may want to take special precautions if you have any of these conditions.
- Tell your doctor if you have an infection at the present time. If you take Diclonova while you have an infection, some of the signs of the infection may be hidden (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

Tell your doctor if you are pregnant or are breast-feeding.

Like most NSAID medicines, Diclonova is not recommended for use during pregnancy or breast-feeding. Use of NSAIDs may increase the risk of miscarriage particularly when taken close to the time of conception. Your doctor will discuss with you the benefits and risks of taking it.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines that are important to mention include:

- Aspirin, salicylates, ibuprofen, or other NSAID medicines
- Warfarin, a medicine used to stop blood clots
- Digoxin, a medicine for your heart
- Lithium, a medicine used to treat some types of depression



- Diuretics, also called fluid or water tablets
- Tablets used to treat diabetes (such as metformin)
- Methotrexate, a medicine used to treat arthritis and some cancers
- Cyclosporin, tacrolimus, medicines used to suppress the immune system
- Trimethoprim, a medicine used to prevent or treat urinary tract infections
- Certain antibiotics called quinolones
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure and heart failure)
- Corticosteroids (medicines used to provide relief for inflamed areas of the body)
- Sulfapyrazone (a medicine used to treat gout)
- Phenytoin (a medicine used to treat seizures).
- Rifampicin (an antibiotic medicine used to treat bacterial infections). Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Diclonova.

If you have not told your doctor about any of these things, tell them before you take Diclonova.

- **How to take Diclonova**

Follow all directions given to you by your doctor and pharmacist carefully. These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will assess your situation and the lowest effective dose for the shortest possible duration will be prescribed.

- For arthritis or other painful conditions where swelling is a problem:

Adults

Your doctor may start your treatment with anywhere from 75mg to 150mg per day, depending on your situation. After the early stages of treatment it is usually possible to reduce the daily dose to 75mg to 100mg per day.



Children

12.5mg and 25mg suppositories are for use in children over 5 years of age and weighing 18kg or more with chronic juvenile rheumatoid arthritis.

* For menstrual cramps (period pain)

* Adults

At the start of treatment the daily dose is usually between 50mg and 100mg. If necessary, it can be raised over several menstrual periods to a maximum of 200mg each day.

- For migraine attacks

Adults

At the first signs of an impending attack the starting dose is usually 100mg. Your doctor may give you additional doses up to 100mg on the same day if required. If you require further therapy on the following days your doctor will give you up to 150 mg in divided doses depending on your situation.

How to take it

Diclonova suppositories are usually used at bedtime to relieve pain during the night and early morning stiffness.

If possible, go to the toilet and empty your bowels before using the suppository. They work best if your bowels are empty.

Follow these steps:

- Wash your hands thoroughly with soap and water.
- If the suppository feels soft, chill it **BEFORE** removing the wrapper by placing it in the fridge or holding it under cold water for a few minutes.
- Put on a disposable glove, if desired (available from a pharmacy)
- Remove all of the wrapper from the suppository.
- Lie on your side and raise your knees to your chest.
- Push the suppository, blunt end first, gently into your rectum (back passage).
- Remain lying down for a few minutes so that the suppository dissolves.
- Wash your hands thoroughly.

Try not to go to the toilet and open your bowels for at least one hour after using the suppository.

The suppository takes about one hour to be completely absorbed and do its work.

If you are not sure how to use a suppository, ask your doctor or pharmacist.



How long to take it

Do not take Diclonova for longer than your doctor says.

If you are taking Diclonova for arthritis, it will not cure your disease but it should help to control pain and inflammation. It usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine. For menstrual cramps (period pain), the suppositories are usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.

If you take Diclonova for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects. If you have questions about how long to take Diclonova, talk to your doctor or your pharmacist.

If you forget to take it

If it is almost time for your next dose (eg. within 2 or 3 hours), skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or go the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Diclonova. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Diclonova

Things you must do

If you become pregnant while taking Diclonova, tell your doctor immediately.

Your doctor can discuss with you the risks of taking it while you are pregnant.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Diclonova. Take Diclonova exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, your condition may not improve or you may have unwanted side effects.

If, for any reason, you have not taken your medicine exactly as prescribed, tell your doctor.



Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

If you feel the medicine is not helping, tell your doctor.

This will help your doctor to determine the best treatment for you.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

If you have established heart disease or significant risks for heart disease, make sure to tell your doctor.

Your doctor will periodically re-evaluate whether you should continue treatment with Diclonova, especially in case you are treated for more than 4 weeks.

If, at any time while taking Diclonova you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately. If you are going to have surgery, make sure the surgeon and anaesthetist know that you are taking Diclonova.

NSAID medicines can slow down blood clotting.

If you get an infection while taking Diclonova, tell your doctor.

This medicine may hide some of the signs of an infection (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

Tell all of the doctors, dentists and pharmacists that are treating you that you are taking Diclonova.

Things you must not do

Do not take any other medicines used to treat arthritis while you are taking Diclonova without first telling your doctor. This includes:

- Aspirin (also called ASA or acetylsalicylic acid)
- Other salicylates
- Any other NSAID medicine
- If you take these medicines together with Diclonova, they may cause unwanted effects. If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, ask your doctor.

Do not stop any other forms of treatment for arthritis that your doctor has told you to follow.

This medicine does not replace exercise or rest programs or the use of heat/cold treatments.

Do not use Diclonova to treat any other complaints unless your doctor says you can. Do not give this medicine to anyone else.



It may harm them, even if their symptoms seem to be the same as yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Diclonova affects you. As with other NSAID medicines, Diclonova may cause dizziness, drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Diclonova. This medicine helps most people, but it may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- Stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- Loss of appetite
- Constipation, diarrhoea, pain in the stomach, wind
- Dizziness, light headedness
- Drowsiness, sleepiness, disorientation
- Buzzing or ringing in the ears
- Change in mood, for example, feeling depressed, anxious or irritable
- Trembling, sleeplessness, nightmares
- Headache
- Sore mouth or tongue
- Hair loss or thinning
- Altered taste sensation

Tell your doctor immediately if you notice any of the following:

- Severe pain or tenderness in the stomach
- Signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal; reddish or purplish blotches under the skin signs of anaemia such as tiredness, being short of breath, looking pale
- A change in the colour of urine passed, blood in the urine



- A change in the amount or frequency of urine passed, burning feeling when passing urine
- * Signs of a liver problem such as tiredness, lack of energy, itching of the skin, yellowing of the skin and eyes, pain in the abdomen
- Unusual weight gain, swelling of ankles or legs
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- Eye problems such as blurred or double vision
- Severe dizziness, spinning sensation
- Severe or persistent headache
- Tingling or numbness of the hands or feet
- Fast or irregular heart beat, also called palpitations
- Difficulty hearing
- Irritation or discomfort in the rectum (back passage) or worsening of haemorrhoids (piles). These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Diclonova and tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital:

- Sudden and oppressive chest pain (signs of myocardial infarction or heart attack) □
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- Vomiting blood or material that looks like coffee grounds
- Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Asthma, wheezing, shortness of breath
- Sudden or severe itching, skin rash or hives
- Fainting or seizures (fits)
- Pain or tightness in the chest
- Inability or difficulty to speak
- Paralysis (signs of cerebral attack)
- Stiff neck (signs of meningitis)
- Raised blood pressure

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice anything else that is making you unwell.
Some people may get other side effects of Diclonova.



After using Diclonova Storage

- Keep your medicine in the original container until it is time to take it.
- Store the container in a cool dry place.
- Do not store Diclonova or any other medicine in the bathroom or any other place that is hot or steamy.
- Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines. They will keep well if the temperature is cool and dry.
- **Keep the medicine where children cannot reach it.**
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Diclonova or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Diclonova 50mg and 100mg Suppositories: White bullet shaped suppositories , packs of 20 strips x 5 suppositories .

Ingredients Diclonova Suppositories contain 50 mg, or 100mg diclofenac sodium as the active ingredient in a suppository base.

Pharmanova Limited

Address: P.O. Box AT 579, Achimota Market, Accra

Country: Ghana

Telephone: +233 (0)302 766568, 766589

Fax: +233 (0)302766589

E-mail: info@pharmanovagh.com